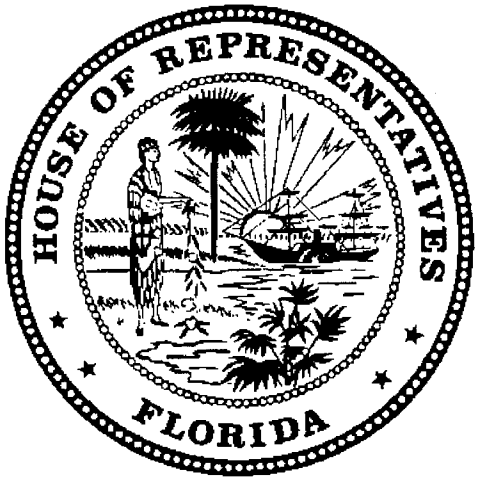

Health Care General Committee

Wednesday, February 22, 2006
10:30 AM – 12:00 PM
306 HOB

COMMITTEE MEETING PACKET

Allan G. Bense
Speaker

Gayle B. Harrell
Chair

AGENDA

Health Care General Committee
February 22, 2006
10:30 a.m. – 12:00 p.m.
306 HOB

I. Call to order/Roll Call

II. Opening Remarks

III. Consideration of the following bills:

- HB 241 - - Florida KidCare Program by Vana
- HB 311 - - Vaccine Production Facilities by Cretul

IV. Consideration of the following proposed committee bill:

- PCB HCG 06-01 - - Emergency Management

V. Presentation of OPPAGA Report No. 06-07
Inflated Pricing, Confidential Information Prevent Medicaid from Ensuring Lowest Prescription Drug Prices

VI. Presentation by the Department of Health
Crohn's Disease and Ulcerative Colitis Report

VII. Presentation by the Florida Council for Community Mental Health
Mental Health and Hospital Emergency Care

VIII. Closing Remarks and Adjournment

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 241 Florida KidCare Program
SPONSOR(S): Vana and others
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care General Committee		Brown-Barrios	Brown-Barrios
2) Health Care Appropriations Committee			
3) Fiscal Council			
4) Health & Families Council			
5)			

SUMMARY ANALYSIS

Florida KidCare was created in 1998 to provide health benefits to uninsured children through the State Children's Health Insurance Program (SCHIP) or Medicaid. KidCare has four program components. These components include Medicaid, MediKids, Healthy Kids, and the Children's Medical Services (CMS) Network. Participation by children in these programs is contingent on age, family income, and special health care needs.

HB 241 amends s. 409.814, F.S., to allow a family with a child who is not eligible for the KidCare program because the family income is above 200 percent of the Federal Poverty Level (FPL) to apply for health insurance coverage from KidCare programs and requires the KidCare program to allow their participation in the program. Current law allows these families to apply for MediKids and Healthy Kids but does not require these programs to allow their participation. In practice, only Healthy Kids has enrolled children from families with income above 200 percent of the FPL. Thus, the impact of this bill will be realized more by the MediKids program which has not enrolled children from families with income above 200 percent of the FPL. A family with income above 200 percent of the FPL must pay the full premium without any premium assistance to receive health insurance coverage under KidCare.

Current law excludes a child from a family whose income is above 200 percent of the FPL from participating in the Medicaid component of KidCare. HB 241 does not change this.

The bill has no fiscal impact.

If enacted, the bill takes effect July 1, 2006.

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Empower families - The bill creates an opportunity for certain families to secure health insurance coverage for their children.

B. EFFECT OF PROPOSED CHANGES:

Although this bill affects the KidCare program, the most significant impact is on MediKids. Unlike Healthy Kids that has allowed the enrollment of children from families with income above 200 percent of the FPL, MediKids has not enrolled children from families with income above 200 percent of the FPL. This bill would allow families to apply for health insurance coverage from the MediKids program and requires the MediKids program to allow their participation in the program.

BACKGROUND

The Florida KidCare Program

The State Children's Health Insurance Program (SCHIP) under Title XXI of the Social Security Act is a Federal/State partnership which provides insurance to uninsured children under age 19 whose family income is above Medicaid limits but below 200 percent of the FPL. Under SCHIP, the Federal government provides a capped amount of funds to States on a matching basis[1]. SCHIP expands insurance coverage for low-income children who do not qualify for Medicaid. Florida's SCHIP eligible children are served in the Florida KidCare Program.

Medicaid under Title XIX of the Social Security Act is a Federal/State entitlement program that pays for medical assistance for certain individuals and families with low incomes and resources.

Florida KidCare was created in 1998 to provide health benefits to uninsured children through either SCHIP or Medicaid. The statutory framework for KidCare is delineated in sections 409.810 through 409.821, F.S. KidCare has four components:

- Medicaid:
  - Birth to age 1, with family incomes up to 200 percent of the FPL.
  - Ages 1 through 5, with family incomes up to 133 percent of the FPL.
  - Ages 6 through 18, with family incomes up to 100 percent of the FPL.
  - Ages 19 through 20, with family incomes up to 24 percent of the FPL.
- MediKids:
  - Children ages 1 through 4 with family incomes above 133 percent to 200 percent of the FPL.
- Healthy Kids:
  - Children age 5, with family incomes above 133 percent to 200 percent of the FPL.
  - Children age 6 through 18, with family incomes above 100 percent to 200 percent of the FPL.
  - A limited number of children who have family incomes over 200 percent of the FPL are enrolled in the unsubsidized full-pay option in which the family pays the entire cost of the premium, including administrative costs.
- Children's Medical Services (CMS) Network:
  - Children ages birth through age 18 who have serious health care problems. For Title XXI-funded eligible children with special health care needs, the CMS Network receives a

[1] The federal allocation for FY 05/06 is $249,329,871 and the federal matching rate is 71.22%.

capitation payment from the Agency for Health Care Administration to provide services for them. For children who do not qualify for Title XIX or Title XXI-funded coverage, services are limited and subject to the availability of funds

2006 Federal Poverty Level

Persons in Family or Household	100%	200%
1	$ 9,800	19,600
2	13,200	26,400
3	16,600	33,200
4	20,000	40,000
5	23,400	46,800

The Agency for Health Care Administration (AHCA) administers Medicaid and MediKids. AHCA is also the lead State agency for the federally funded portion of the KidCare program. The Florida Healthy Kids Corporation (FHKC), under contract with AHCA, administers the Healthy Kids component. FHKC responsibilities include eligibility determination, collection of premiums, contracting with authorized insurers, and the development of benefit packages. CMS is under the Department of Health and administers the CMS Network. For Title XXI-funded children with special health care needs, the CMS Network receives a capitation payment from the Agency for Health Care Administration of approximately $518.00 per child, per month. Children's Medical Services also administers a state-funded "Safety Net" program for children who do not qualify for Title XIX- or Title XXI-funded coverage, but services are limited and subject to the availability of funds.

Section 409.814(5), F.S., allows a child whose family income is above 200 percent of the FPL to participate in MediKids and Healthy Kids if the family pays the full premium without any premium assistance. In practice, only Healthy Kids has enrolled children from families with income above 200 percent of the FPL. The Healthy Kids full pay premium is $110 per child per month. MediKids has not enrolled children from families with income above 200 percent of the FPL. Current law limits the participation of families with income above 200 percent of the FPL in MediKids and Healthy Kids to no more than 10 percent of total enrollees in the programs in order to avoid adverse selection[2]. Section 409.814(5), F.S., excludes a child whose family income is above 200 percent of the FPL from participating in the Medicaid component of KidCare. It is unclear whether current law allows families with income above 200 percent of the FPL to participate in the CMS Network (see DRAFTING ISSUES OR OTHER COMMENTS)

The differences in the eligibility and ability to offer a full pay premium option for families with incomes above 200 percent of FPL, has created the potential for confusion. Families may find that they can insure one child but not the other.

Summary of KidCare Full Pay Option

Florida KidCare	**Children from families with incomes above 200% of FPL allowed to participate.**	**Children from families above 200% of FPL actually participating in program.**
Medicaid	No	N/A
MediKids	Yes	No
Healthy Kids	Yes	Yes
CMS Network	Unclear	No

[2] Adverse selection occurs when too many children who are likely to incur high medical cost join the same health insurance plan. Adverse selection can cause what insurers refer to as a "death spiral". As more sick children join, the health insurance plan must raise premiums to cover cost. As premiums increase, families with healthier children leave to join less costly plans. The plan is left with only sick children and has difficulty spreading risk to cover their cost and ultimately may fail.

C. SECTION DIRECTORY:

Section 1. Amends subsection (2) and (5) of section 409.814, F.S.

Section 2. Establishes an effective date for the act of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None

2. Expenditures:

   None

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None

2. Expenditures:

   None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health care providers, including health maintenance organizations, which arrange most of the health services for children enrolled in MediKids and the Children's Medical Services Network, should realized an increase in revenue as a result of increased enrollment in KidCare by families that are willing to pay the full premium.

Children with families above 200 percent of the FPL must pay the full pay premium without any premium assistance to participate in MediKids or Healthy Kids.

D. FISCAL COMMENTS:

AHCA for MediKids and DOH for the CMS Network (if included) would need to obtain actuarial services to calculate an appropriate premium for the full pay option that would support the cost of services, reinsurance, and other administrative costs. DOH estimates the cost to determine the actuarial based premium at $9,000.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

The bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. The bill does not reduce the percentage of a state tax shared with counties or municipalities. The bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Sufficient rulemaking authority exists to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

It is unclear whether the provisions of this bill apply to the CMS Network program. This is not a problem with the bill but with current law.

Section 409.814(3), F.S., states that a child who is eligible for the Florida KidCare program who is a child with special health care needs, as determined through a medical or behavioral screening instrument, is eligible for health benefits coverage from and shall be referred to the Children's Medical Services Network. Unlike Medicaid, subsection (5) of s. 409.814 (see line 34 of the bill) does not specifically exclude the CMS Network from the full-pay option for those children from families above 200 percent of the FPL.

However, paragraphs (a) – (d) of this subsection (see lines 36 -56 of the bill) does not contain any language limiting the number of children who can participate in the CMS Network whose family income exceeds 200 percent of the FPL. This could imply that the full pay option is not available for the CMS Network or imply that there is no limitation to the number of the full pays the CMS Network can accept which is highly unlikely. Committee staff suggests one of two amendments to correct this ambiguity.

To exclude the CMS Network from the full pay provision:
On line 34 after program, insert: and Children's Medical Services Network program

To include the CMS Network in the full pay provision :
On line 53 after the period, insert: (d) The Department of Health is authorized to place limits on enrollment in the Children's Medical Services Network program by these children in order to avoid adverse selection. In addition, the Department of Health may offer a reduced benefit package to these children in order to limit program costs for such families. The number of children participating in the Children's Medical Services Network program whose family income exceeds 200 percent of the federal poverty level must not exceed 10 percent of total enrollees in the in the Children's Medical Services Network program.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to the Florida KidCare program; amending s. 409.814, F.S.; authorizing eligibility for coverage in the Florida KidCare program for additional categories of children; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsections (2) and (5) of section 409.814, Florida Statutes, are amended to read:

409.814 Eligibility.--A child who has not reached 19 years of age whose family income is equal to or below 200 percent of the federal poverty level is eligible for the Florida KidCare program as provided in this section. For enrollment in the Children's Medical Services Network, a complete application includes the medical or behavioral health screening. If, subsequently, an individual is determined to be ineligible for coverage, he or she must immediately be disenrolled from the respective Florida KidCare program component.

(2) A child who is not eligible for Medicaid, but who is eligible for the Florida KidCare program, may obtain health benefits coverage under any of the other components listed in s. 409.813 if such coverage is approved and available in the county in which the child resides. However, a child who is eligible for Medikids, including those eligible under subsection (5), may participate in the Florida Healthy Kids program only if the child has a sibling participating in the Florida Healthy Kids

program and the child's county of residence permits such enrollment.

(5) A child whose family income is above 200 percent of the federal poverty level or a child who is excluded under the provisions of subsection (4) may apply for coverage and shall be allowed to participate in the Florida KidCare program, excluding the Medicaid program, but is subject to the following provisions:

(a) The family is not eligible for premium assistance payments and must pay the full cost of the premium, including any administrative costs.

(b) The agency is authorized to place limits on enrollment in Medikids by these children in order to avoid adverse selection. The number of children participating in Medikids whose family income exceeds 200 percent of the federal poverty level must not exceed 10 percent of total enrollees in the Medikids program.

(c) The board of directors of the Florida Healthy Kids Corporation is authorized to place limits on enrollment of these children in order to avoid adverse selection. In addition, the board is authorized to offer a reduced benefit package to these children in order to limit program costs for such families. The number of children participating in the Florida Healthy Kids program whose family income exceeds 200 percent of the federal poverty level must not exceed 10 percent of total enrollees in the Florida Healthy Kids program.

(d) Children described in this subsection are not counted in the annual enrollment ceiling for the Florida KidCare program.

Section 2. This act shall take effect July 1, 2006.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 311 Vaccine Production Facilities
SPONSOR(S): Cretul and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 706

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care General Committee		Halperin	Brown-Barrios
2) Health Care Appropriations Committee			
3) Health & Families Council			
4)			
5)			

SUMMARY ANALYSIS

Across the nation, concerns over vaccine shortages and production have increased due to threats of both bioterrorism and pandemic influenza virus. Efforts to bolster vaccine production and accessibility are now a focus of government policy to better address general health issues and the threat to domestic security.

HB 311 addresses the issue of vaccine shortage in Florida by providing incentives for the production of vaccines in Florida. The bill:

- Provides incentives for vaccine production facilities established in or relocated in Florida to produce vaccines for the prevention of communicable disease.
- Exempts vaccine manufactures located in Florida from liability
- Establishes a loan and loan guarantee program within the Department of Health (DOH) to increase the financing available to fund the costs incurred by new or expanded production facilities in the state that produce vaccines.
- Requires the Department of Health to purchase a portion of vaccines produced in the state by vaccine manufactures for a specified period of time.

If enacted, the bill takes effect upon becoming law.

This bill has a fiscal impact.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Maintain Public Security: The bill may increase the physical security of Floridians were it to result in an increase in the quantity and accessibility of vaccines.

Provide Limited Government: The bill may increase the work for governmental organizations by creating a loan guarantee program and industry outreach program to be administered by the Department of Health.

B. EFFECT OF PROPOSED CHANGES:

Effect

This bill addresses the issue of vaccine shortage specifically for Florida. The bill provides incentives for vaccine production facilities established in Florida or relocated to Florida to produce certain vaccines. It exempt vaccine manufactures from liability; establish a loan and loan guarantee program within the Department of Health for the construction or relocation of such facilities; and require the Department of Health to purchase a portion of vaccines produced in the state by these facilities for a specified period of time.

Background

Social Benefits of Vaccines

In the United States, vaccines exist for preventing 11 once common childhood diseases and for preventing diseases responsible for high rates of sickness and death among adults. Vaccines provide a wide range of social benefits, including reducing the medical costs of diseases that are prevented, and enhancing the length, quality, and productivity of life.[1]

The Costs and Challenges of Vaccine Production

Vaccine production is "painfully slow compared with other sectors of drug and medical technology markets."[2] A 1985 Institute of Medicine (IOM) report on vaccine development describes the "technical problems, high research and development costs, the expense and logistics of clinical testing and surveillance of reactions, the risk of litigation" in the vaccine market.[3] A modern manufacturing vaccine production facility can cost $300 million to $500 million and take three to five years to build.[4] In 2002, the Tufts University Center for the Study of Drug Development estimated that it took an investment of $802 million to develop a new vaccine. An expert panel convened by the Department of Defense (DoD) estimated development costs at $300-$400 million per vaccine.[5]

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[1] Institute of Medicine, August 2003. "Financing Vaccines in the 21st Century: Assuring Access and Availability." National Academies Press. Full text available at http://www.nap.edu.

[2] Gottlieb, S., and Calfee J.E.. 11/1/2004. "Putting Markets to Work in Vaccine Manufacturing." *American Enterprise Institute for Public Policy Research.* http://www.aei.org/publications/pubID.21659/pub_detail.asp.

[3] Institute of Medicine, Division of Health Promotion and Disease Prevention, *Vaccine Supply and Innovation* (Washington, D.C.: National Academy Press, 1985).

[4] Agres, Ted. "Vaccine Supplies Remain Sickly." Column by *Washington Times deputy managing editor.* Published in Drug Discovery & Development.
http://www.dddmag.com/ShowPR.aspx?PUBCODE=016&ACCT=1600000100&ISSUE=0505&RELTYPE=PR&ORIGRELTYPE=PNP&PRODCODE=00000000&PRODLETT=AG

[5] Rettig, R.A. and Brower, J.B. 2003. "The Acquisition of Drugs and Biologics for Chemical and Biological Warfare Defense: Department of Defense Interactions with the Food and Drug Administration." Prepared for the Office of the Secretary of Defense by the National Defense Research Institute and RAND Health. Available online at
http://www.rand.org/pubs/monograph_reports/2005/RAND_MR1659.sum.pdf.

The U.S. has a very expensive process for regulating the manufacture of biologics, and especially the flu vaccine because companies must gain approval for a new product every year from the FDA. In addition, techniques and equipment for manufacturing other biologics[6] have advanced dramatically. The processes for producing vaccines must adhere to strict regulation of development and manufacturing.[7] While advances in these technologies help ensure the public safety, they also add costs to the manufacturing process.

Decline of Manufacturing Capacity

The number of producers of recommended vaccines for the US market has declined from more than 25 companies 30 years ago to only 5 today.[8] The factors for the reduction of manufactures of vaccines include:

- Narrow profit margins associated with the cost of producing vaccines and uncertain demand.
- Fear of litigation.
- A number of mergers and acquisitions of vaccine manufacturers into larger companies.
- Globalization of the market.

Liability

Liability has discouraged manufacturers from investing in vaccine development. Vaccines are given to millions of healthy people, and because they are grown from living organisms instead of synthesized chemicals, they are prone to uncertainties in the manufacturing process. This makes vaccines targets for tort litigation on behalf of anyone who suffers any sort of illness after vaccination. Congress implemented the National Vaccine Injury Compensation Program (VICP) on October 1, 1988 as an effort to make sure that children injured as a result of a routinely recommended vaccine could be quickly compensated. This no-fault compensation system restricted the scope for liability and helped stem the exodus of manufacturers from the childhood vaccine industry. However after 20 years, the VICP is perhaps insufficient to cover recent trends in litigation against vaccine manufacturers, and the viability of the VICP is threatened.[9]

Federal law provisions enacted through the Department of Defense Appropriations Act, 2006 (See Comment Section), provides additional protection from liability for vaccine and pharmaceutical manufacturers under certain conditions.[10] Federal law further details that because the FDA is responsible for testing the safety of vaccines and pharmaceuticals, lawsuits against manufacturers of FDA-approved products are to be held in federal and not state court.

Federal Role in Vaccine Administration

The FDA is legally responsible for regulating the pharmaceutical industry and ensuring that drugs and vaccines released to the public are safe and effective.

The National Immunization Program of the Centers for Disease Control and Prevention (CDC) administers the vaccine purchase program for the federal government. Each state government has its own immunization program, which estimates the level of vaccines needed to assure access to immunization among underserved groups of children and adults. The CDC negotiates a federal contract for each vaccine product, using large volume purchase as leverage to obtain discounts on the

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[6] Biologics (biological products) include a wide range of products such as vaccines, blood and blood components, gene therapy, allergenics, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics tend to be heat sensitive and susceptible to microbial contamination.

[7] Gottlieb, S., and Calfee J.E.. 11/1/2004. "Putting Markets to Work in Vaccine Manufacturing." *American Enterprise Institute for Public Policy Research.* http://www.aei.org/publications/pubID.21659/pub_detail.asp.

[8] Institute of Medicine, August 2003. "Financing Vaccines in the 21st Century: Assuring Access and Availability." National Academies Press. Full text available at http://www.nap.edu.

[9] Offit, Dr. Paul. "Vaccine History Shows Need to Update VICP." November 15, 2005. *The Hill.* http://www.hillnews.com/thehill/export/TheHill/News/Frontpage/111505/offit.html

[10] H.R. 2863, Department of Defense Appropriations Act, 2006.

manufacturer's list price. The states also rely upon the federal discount price for vaccines purchased with state revenues. Although the discount has declined significantly in recent years, the discount pricing process also has the effect of deflating payments to pharmaceutical which tends to discourage future investments in vaccine development.

Florida's Role in Vaccine Administration

States have an important role in setting immunization policy and establishing an immunization infrastructure. Policies for immunization requirements, including minimum school and day care entry requirements, are made almost exclusively at the state level, although cities occasionally impose additional requirements. Each state also establishes an immunization infrastructure to monitor infectious disease outbreaks, administer federal immunization grants, manage centralized supplies of vaccine, direct professional and public education efforts, and otherwise promote immunization policies. The DOH plays a key role in this aspect. The DOH Bureau of Statewide Pharmaceutical Services has been responsible for administering and managing annual statewide contracts for pharmaceuticals, including vaccines since 1993. The DOH Bureau of Immunization promotes, monitors and provides technical assistance to facilitate the completion of childhood immunizations and adult immunization.

Recently, Florida joined the Minnesota Multi-state Contracting Alliance for Pharmacy (MMCAP), a free and voluntary group purchasing organization for pharmaceuticals. Drugs purchased through MMCAP are for the benefit of all state agencies and political subdivisions that utilize pharmaceuticals for their clients. Previous to joining MMCAP, Florida did its own drug bids. Existing Florida contracts for pharmaceuticals were cancelled effective September 14, 2003. At this time, Florida only accesses the pharmaceuticals and vaccines offered by MMCAP.[11]

Section 288.108

288.108, F.S., delineates a framework to attract, retain, and provide favorable conditions for the growth of certain high-impact facilities provides widespread economic benefits to Florida citizens. This section allows the Office or Tourism Trade and Economic Development (office) to engage in activities to attract high impact[12] business to Florida. The office may, in consultation with Enterprise Florida, Inc., negotiate qualified high-impact business performance grant awards for any single qualified high-impact business. In negotiating grant awards, the office is required to consider the following guidelines in conjunction with other relevant applicant impact and cost information and analysis.

- A qualified high-impact business making a cumulative investment of $100 million and creating 100 jobs may be eligible for a total qualified high-impact business performance grant of $1 million to $2 million.
- A qualified high-impact business making a cumulative investment of $800 million and creating 800 jobs may be eligible for a qualified high-impact business performance grant of $10 million to $12 million.
- A qualified high-impact business, engaged in research and development, making a cumulative investment of $75 million and creating 75 jobs may be eligible for a total qualified high-impact business performance grant of $2 million to $3 million.
- A qualified high-impact business, engaged in research and development, making a cumulative investment of $150 million and creating 150 jobs may be eligible for a qualified high-impact business performance grant of $3.5 million to $4.5 million.

Section 381.003

Section 381.003, F.S., requires DOH to conduct:

- Communicable disease prevention and control program as part of fulfilling its public health mission.
- Programs for the prevention, control, and reporting of diseases of public health significance.

[11] More information on MMPAC contract is available online at: http://dms.myflorida.com/dms/purchasing/state_contracts_agreements_and_price_lists/state_term_contracts/pharmaceutical_purchasing_program_mmcap/complete_contract_contract_notice

[12] Defined as a business that makes invest a minimum of a $75 million and creates a minimum of 75 jobs.

- Programs for the prevention and control of vaccine-preventable diseases, including programs to immunize school children.

C. SECTION DIRECTORY:

Section 1.

Subsection (1). Requires DOH to conduct an outreach campaign to encourage pharmaceutical companies located in the state to produce vaccines for the prevention of communicable diseases. The bill further requires DOH to encourage such companies located outside the state to establish vaccine manufacturing companies within the state.

Subsection (2). Limits the civil liabilities of any business located in the state that manufactures vaccines approved by the United States Food and Drug Administration (FDA) to prevent communicable diseases.

Subsection (3). Requires DOH to establish a loan guarantee program for manufacturers who locate to the State of Florida for the purposes or producing vaccines for the prevention of communicable diseases.

Subsection (4). Requires DOH to enter into an agreement with vaccine manufacturers located in Florida to purchase a portion of vaccines from these companies for a specified period of time. The purchase of such vaccines from pharmaceutical companies referenced in the bill would not be subject to the competitive procurement process currently used by the department.

Section 2. Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   See Fiscal Comments

2. Expenditures:

   See Fiscal Comments

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None

2. Expenditures:

   None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill could encourage vaccine manufactures to construct facilities in Florida or relocate, as a result there would be an increase in economic activity in specific locations in the form of construction, job creation and related services and commerce.

D. FISCAL COMMENTS:

Increased economic activity as a result of vaccine manufactures to construct facilities in Florida or relocate to Florida would generate tax revenue for the state.

According to DOH, the bill would have a fiscal impact on the DOH. However, no specific estimates where provided. The following provisions of the bill would require a specific appropriation to DOH.

- The bill requires DOH to establish a loan guarantee program for manufacturers who locate to the State of Florida for the purposes or producing vaccines for the prevention of communicable diseases.

- The bill requires DOH to enter into an agreement with vaccine manufacturers located in Florida to purchase a portion of vaccines from these companies for a specified period of time. According to DOH analysis this could force the state to purchase vaccines it does not want at prices that are not competitive; and could leave Florida dependent on single manufacturers.

- If the bill becomes law and the DOH is required to purchase vaccines from specified companies, it could jeopardize the Florida's membership in the MMCAP buying group for both vaccines and for other pharmaceutical products. This could result in substantial changes in the price and purchasing of pharmaceuticals.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   The bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. The bill does not reduce the percentage of a state tax shared with counties or municipalities. The bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None

B. RULE-MAKING AUTHORITY:

No additional rule-making authority is required as a result of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

On December 30, 2005, President Bush signed into law the "Public Readiness and Emergency Preparedness Act" (PREP Act) as part of the 2006 Defense Appropriations Act (H.R. 2863). The PREP Act offers targeted liability protections to those involved in the development, manufacturing, and deployment of pandemic and epidemic products and security countermeasures. The Act creates a shield of immunity for claims arising out of, related to, or resulting from the administration or the use of a covered countermeasure (i.e., vaccines, countermeasures, devices and certain other products). This immunity covers a wide range of uses, including design, development, testing, manufacturing, distribution, administration, use, and other activities so that the protections can be applied as broadly as possible.

The immunity created by the Act can be overcome, but only upon a showing of willful misconduct that proximately caused a serious injury or death. The Act creates a single new Federal cause of action related to claims arising out of the use of pandemic and epidemic products and security countermeasures. To meet the "willful misconduct" exception, a plaintiff must show that acts or omissions were undertaken to "intentionally achieve a wrongful purpose." Most significantly, prior to any claim of willful misconduct, the Food and Drug Administration or Department of Justice must take and complete a specific enforcement action establishing the willful misconduct. Plaintiffs must specifically detail their claims, and there are mandatory penalties for counsel which file frivolous or baseless suits.

If claims can proceed, there are other restrictions, such as a limit on damages and reductions for collateral benefits received by a plaintiff.

The liability protections under the PREP Act are triggered when the Secretary of Health and Human Services makes a declaration that a disease or other threat constitutes a public health emergency, or that there is a credible risk of such a threat. This flexibility allows the Secretary to be proactive and prepare the nation's infrastructure for threats that are real, but may not be occurring in the immediate future.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to vaccine production facilities; providing incentives for vaccine production facilities to produce certain vaccines; exempting certain business entities from liability under certain circumstances; establishing a loan and loan guarantee program; requiring the Department of Health to purchase a portion of vaccines produced in the state for a specified period of time; providing an effective date.

WHEREAS, the adequacy of our country's supply of vaccines has been called into question because of the growing demand for the influenza vaccine and other vaccines in response to the exhortations of public health officials, and

WHEREAS, this growing demand for vaccines has increased the pressure on the nation's domestic suppliers and created the potential for a major public health crisis, and

WHEREAS, the issue of the inadequacy of vaccine supplies to meet the needs of our citizens, and particularly to protect the public against influenza, which kills some 36,000 Americans each year, has now advanced to the forefront of the public health agenda, and

WHEREAS, urgent action is needed to augment the limited domestic vaccine supply, especially the supply of influenza vaccine, in order to protect the health of the American public, not only those individuals who are most at risk from vaccine-preventable diseases but also the rest of the population as well, and

WHEREAS, given the impediment to the increased production of vaccines created by the regulatory requirements imposed by the United States Food and Drug Administration, the state should offer financial incentives to pharmaceutical manufacturers to increase the production of vaccines and thereby ensure their availability in quantities that are adequate to protect the most vulnerable individuals in the state and to permit the rest of the citizens of the state who wish to be vaccinated to receive this protection as well, NOW, THEREFORE,

Be It Enacted by the Legislature of the State of Florida:

Section 1. Vaccine production facilities; incentives for vaccine production; liability; loan program.--

(1) The Department of Health shall conduct an outreach campaign to encourage pharmaceutical companies located in this state to produce vaccines for the prevention of communicable diseases and to encourage pharmaceutical companies located outside of this state to establish facilities in this state to produce vaccines for the prevention of communicable diseases.

(2) A business, corporation, sole proprietorship, partnership, subchapter S corporation, limited liability corporation, nonprofit corporation, consortium, or other business entity located in this state that in good faith develops or produces vaccines for the prevention of communicable diseases shall not be held liable for civil damages for any act or omission, except for knowing and willful acts or omissions, in the development or production of vaccines for the prevention

of communicable diseases that are approved for market distribution by the United States Food and Drug Administration.

(3) The Department of Health shall establish a loan and loan guarantee program to increase the financing available to fund the costs incurred by new or expanded production facilities in the state that produce vaccines for the prevention of communicable diseases, including, but not be limited to, the influenza virus. Loans or loan guarantees shall be made available to pharmaceutical companies, partnerships of such companies, and consortia of such companies, provided that the production facility meets the requirements of the United States Food and Drug Administration to ensure the safety, efficacy, purity, and potency of the vaccines produced at the facility.

(4) The Department of Health shall enter into an agreement with each production facility that commences production of vaccines for the prevention of communicable diseases to purchase a portion of all vaccines produced at the facility that are approved by the United States Food and Drug Administration to ensure the safety, efficacy, purity, and potency of the vaccine. Such an agreement may be for no more than 1 year. The department shall take all actions that are necessary to encourage physicians, nurses, health care facilities, pharmacies, and other entities that dispense vaccines in the state to obtain a portion of their vaccine supply from vaccine production facilities currently located in the state or facilities that commence production of vaccines in the state after July 1, 2006.

Section 2. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 01(for drafter's use only)

Bill No. **HB 311**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care General Committee

Representative(s) Cretul offered the following:

Amendment (with title amendments)

Remove line(s) 41-82 and insert:

Section 1. Vaccine production facilities; incentives for vaccine production; liability.--

(1) Enterprise Florida, Inc., as the principal economic development organization for the state under s. 288.9015, Florida Statutes, shall conduct an outreach campaign to encourage pharmaceutical companies located in this state to produce vaccines for the prevention of communicable diseases and to encourage pharmaceutical companies located outside of this state to establish facilities in this state to produce vaccines for the prevention of communicable diseases.

(2) A business, corporation, sole proprietorship, partnership, subchapter S corporation, limited liability corporation, nonprofit corporation, consortium, or other business entity located in this state that in good faith develops or produces vaccines for the prevention of communicable diseases shall not be held liable for civil damages for any act

or omission, except for knowing and willful acts or omissions, in the development or production of vaccines for the prevention of communicable diseases that are approved for market distribution by the United States Food and Drug Administration.

========== T I T L E A M E N D M E N T ==========

Remove line(s) 6-8

A bill to be entitled

An act relating to emergency management; amending s. 252.355, F.S.; specifying additional agencies that are required to provide registration information to special needs clients and persons with disabilities or special needs who receive services from such agencies for purposes of inclusion within the registry of persons with special needs maintained by local emergency management agencies; providing that the Department of Community Affairs shall be the designated lead agency responsible for community education and outreach to the general public, including special needs clients, regarding registration as a person with special needs, special needs shelters, and general information regarding shelter stays; requiring the department to disseminate educational and outreach information through local emergency management offices; requiring the department to coordinate community education and outreach related to special needs shelters with specified agencies and entities; providing that specified confidential and exempt information relating to registration of persons with special needs be provided to the Department of Health; creating s. 252.3568, F.S.; providing for evacuation for persons with pets; amending s. 381.0303, F.S.; providing for the operation, maintenance, and closure of special needs shelters; removing a condition of specified funding as a prerequisite to the assumption of lead responsibility by the Department of Health for specified coordination with

respect to the development of a plan for the staffing and medical management of special needs shelters; providing that the local Children's Medical Services offices shall assume lead responsibility for specified coordination with respect to the development of a plan for the staffing and medical management of pediatric special needs shelters; requiring such plans to conform to the local comprehensive emergency management plan; requiring county governments to assist in the process of coordinating the recruitment of health care practitioners to staff local special needs shelters; providing that the appropriate county health department, Children's Medical Services office, and local emergency management agency shall jointly determine the responsibility for medical supervision in a special needs shelter; providing that state employees with a preestablished role in disaster response may be called upon to serve in times of disaster in specified capacities; requiring the Secretary of Elderly Affairs to convene a multiagency emergency special needs shelter response team or teams to assist local areas that are severely impacted by a natural or manmade disaster that required the use of special needs shelters; providing duties and responsibilities of multiagency response teams; authorizing local emergency management agencies to request the assistance of a multiagency response team; providing for the inclusion of specified state agency representatives on each multiagency response team; authorizing hospitals and nursing homes that are used to

shelter special needs persons during or after an evacuation to submit invoices for reimbursement to the Department of Health; requiring the department to specify by rule expenses that are reimbursable and the rate of reimbursement for services; prescribing means of and procedures for reimbursement; providing eligibility for reimbursement of health care facilities to whom special needs shelter clients have been discharged by a multiagency response team upon closure of a special needs shelter; providing requirements with respect to such reimbursement; prescribing means of and procedures for reimbursement; disallowing specified reimbursements; revising the role of the special needs shelter interagency committee with respect to the planning and operation of special needs shelters; providing required functions of the committee; providing that the committee shall recommend guidelines to establish a statewide database to collect and disseminate special needs registration information; revising the composition of the special needs shelter interagency committee; requiring the inclusion of specified rules with respect to special needs shelters and specified minimum standards therefore; providing requirements with respect to emergency management plans submitted by a home health agency, nurse registry, or hospice to a county health department for review; removing a condition of specified funding as a prerequisite to the submission of such plans; amending s. 252.385, F.S.; requiring the Division of Emergency Management of the

Department of Community Affairs to prepare and submit a statewide emergency shelter plan to the Governor and the Cabinet for approval; providing plan requirements; requiring the Department of Health to assist the division in determining the estimated need for special needs shelter space; requiring inspection of public hurricane evacuation shelter facilities by local emergency management agencies prior to activation of such facilities; amending s. 400.492, F.S.; providing that nurse registries, hospices, and durable medical equipment providers shall prepare and maintain a comprehensive emergency management plan; providing that home health, hospice, and durable medical equipment provider agencies shall not be required to continue to provide care to patients in emergency situations that are beyond their control and that make it impossible to provide services; authorizing home health agencies, nurse registries, hospices, and durable medical equipment providers to establish links to local emergency operations centers to determine a mechanism to approach areas within a disaster area in order for the agency to reach its clients; providing that the presentation of home care or hospice clients to the special needs shelter without the home health agency or hospice making a good faith effort to provide services in the shelter setting constitutes abandonment of the client; requiring regulatory review in such cases; amending s. 408.831, F.S.; providing that entities regulated or licensed by the Agency for Health

Care Administration may exceed their licensed capacity to act as a receiving facility under specified circumstances; providing requirements while such entities are in an overcapacity status; providing for issuance of an inactive license to such licensees under specified conditions; providing requirements and procedures with respect to the issuance and reactivation of an inactive license; providing fees; creating s. 252.357, F.S., requiring the Florida Comprehensive Emergency Management Plan to permit the Agency for Health Care Administration to initially contact nursing homes in disaster areas for specified monitoring purposes; requiring the agency to publish an emergency telephone number for use by nursing homes; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 252.355, Florida Statutes, is amended to read:

252.355 Registry of persons with special needs; notice.--

(1) In order to meet the special needs of persons who would need assistance during evacuations and sheltering because of physical, mental, <u>cognitive impairment,</u> or sensory disabilities, each local emergency management agency in the state shall maintain a registry of persons with special needs located within the jurisdiction of the local agency. The registration shall identify those persons in need of assistance and plan for resource allocation to meet those identified needs.

To assist the local emergency management agency in identifying such persons, home health agencies, hospices, nurse registries, home medical equipment providers, the Department of Children and Family Services, Department of Health, Agency for Health Care Administration, Department of Education, Agency for Persons with Disabilities, ~~Department of Labor and Employment Security,~~ and Department of Elderly Affairs shall provide registration information to all of their special needs clients and to all people with disabilities or special needs who receive services ~~incoming clients as a part of the intake process~~. The registry shall be maintained year-round. The registration program shall give persons with special needs the option of preauthorizing emergency response personnel to enter their homes during search and rescue operations if necessary to assure their safety and welfare following disasters.

(2) The Department of Community Affairs shall be the designated lead agency responsible for community education and outreach to the general public, including special needs clients, regarding registration and special needs shelters and general information regarding shelter stays. The Department of Community Affairs shall disseminate such educational and outreach information through the local emergency management offices. The department shall coordinate the development of curriculum and dissemination of all community education and outreach related to special needs shelters with the Clearinghouse on Disability Information of the Governor's Working Group on the Americans with Disabilities Act, the Department of Children and Family Services, the Department of Health, the Agency for Health Care

Administration, the Department of Education, the Agency for Persons with Disabilities, and the Department of Elderly Affairs. The special needs shelter is considered a public facility when it is activated for a disaster. Under the Americans with Disabilities Act (ADA), Public Law 101.336, businesses and organizations that serve the public must allow people with disabilities to bring their service animals into all areas of the facility where customers are normally allowed to go.

(3) ~~(2)~~ On or before January 1 ~~May 1~~ of each year each electric utility in the state shall semi-annually notify residential customers in its service area of the availability of the registration program available through their local emergency management agency.

(4) ~~(3)~~ All records, data, information, correspondence, and communications relating to the registration of persons with special needs as provided in subsection (1) are confidential and exempt from the provisions of s. 119.07(1), except that such information shall be available to other emergency response agencies, as determined by the local emergency management director, and to the Department of Health in the furtherance of their duties and responsibilities.

(5) ~~(4)~~ All appropriate agencies and community-based service providers, including home health care providers hospices, nurse registries, and home medical equipment providers, shall assist emergency management agencies by collecting registration information for persons with special needs as part of program intake processes, establishing programs

to increase the awareness of the registration process, and educating clients about the procedures that may be necessary for their safety during disasters. Clients of state or federally funded service programs with physical, mental, cognitive impairment, or sensory disabilities who need assistance in evacuating, or when in shelters, must register as persons with special needs.

Section 2. Section 252.3568, Florida Statutes, is created to read:

252.3568 Emergency sheltering of persons with pets.—

(1) GENERAL PROVISIONS.—In accordance with the provisions of s. 252.35, the division shall address evacuation of persons with pets with the shelter component of the state comprehensive emergency management plan. The Department of Agriculture and Consumer Services shall assist the division in determining strategies regarding this activity.

Section 3. Section 381.0303, Florida Statutes, is amended to read:

381.0303 ~~Health practitioner recruitment for~~ Special needs shelters.--

(1) PURPOSE.--The purpose of this section is to provide for the operation, maintenance, and closure of special needs shelters and to designate the Department of Health, through its county health departments, as the lead agency for coordination of the recruitment of health care practitioners, as defined in s. 456.001(4), to staff special needs shelters in times of emergency or disaster and to provide resources to the department to carry out this responsibility. However, nothing in this

section prohibits a county health department from entering into an agreement with a local emergency management agency to assume the lead responsibility for recruiting health care practitioners.

(2) SPECIAL NEEDS SHELTER PLAN; STAFFING; CLOSURE; STATE AGENCY ASSISTANCE ~~AND STAFFING.--~~Provided funds have been appropriated to support ~~medical services~~ disaster coordinator positions in county health departments,

(a) The department shall assume lead responsibility for the ~~local~~ coordination of local medical and health care providers, the American Red Cross, and other interested parties in developing a plan for the staffing and medical management of special needs shelters. The local Children's Medical Services offices shall assume lead responsibility for the local coordination of local medical and health care providers, the American Red Cross, and other interested parties in developing a plan for the staffing and medical management of pediatric special needs shelters. Plans shall conform to ~~The plan shall be in conformance with~~ the local comprehensive emergency management plan.

(b) ~~(a)~~ County health departments shall, in conjunction with the local emergency management agencies, have the lead responsibility for coordination of the recruitment of health care practitioners to staff local special needs shelters. County health departments shall assign their employees to work in special needs shelters when those employees are needed to protect the health and safety of special needs persons ~~of patients~~. County governments shall assist the Department of

Health with non-medical staffing and operating of special needs shelters. The local health department and emergency management agency shall coordinate these efforts to ensure appropriate staffing in special needs shelters.

(c) ~~(b)~~ The appropriate county health department, Children's Medical Services office, and local emergency management agency shall jointly decide ~~determine~~ who has responsibility for medical supervision in each ~~a~~ special needs shelter and shall notify the Department of Community Affairs Division of Emergency Management and the Department of Health of their decision.

(d) ~~(c)~~ Local emergency management agencies shall be responsible for the designation, operation and infrastructure of special needs shelters during times of emergency or disaster and the closure of the facilities following an emergency or disaster. The emergency management agency and the local health department shall coordinate these efforts to ensure appropriate designation, operation and infrastructure in special needs shelters. County health departments shall assist the local emergency management agency with regard to the management of medical services in special needs shelters. However, nothing in this section prohibits a county health department from entering into an alternative agreement with a local emergency management agency to assume the lead responsibility for special needs shelter supplies and equipment.

(e) State employees with a preestablished role provided by the employee's respective agency in disaster response unless they have other mandated response activities that preclude

participation, are subject to serve in times of disaster commensurate with their knowledge, skills, and abilities and any needed activities related to the situation.

(f) The Secretary of Elderly Affairs, or his or her designee, shall convene, at any time that he or she deems appropriate and necessary, a multiagency special needs shelter discharge planning team or teams to assist local areas that are severely impacted by a natural or manmade disaster that requires the use of special needs shelters. Multiagency special needs shelter discharge planning teams shall provide assistance to local emergency management agencies with the continued operation or closure of the shelters, and with the discharge of special needs clients to alternate facilities if necessary. Local emergency management agencies may request the assistance of a multiagency special needs shelter discharge planning team by alerting statewide emergency management officials of the necessity for additional assistance in their area. The Secretary of Elder Affairs shall work with other state agencies prior to any natural disasters for which warnings are provided to ensure that multiagency special needs shelter discharge planning teams are ready to assemble and deploy rapidly upon a determination by state emergency management officials that a disaster area requires assistance. The Secretary of Elder Affairs may call upon any state agency or office to provide staff to assist a multiagency special needs shelter discharge planning team or teams. Unless the secretary determines that the nature or circumstances surrounding the disaster do not warrant participation from a particular agency's staff, each multiagency

special needs shelter discharge planning team shall include at least one representative from each of the following state agencies:

1. Department of Elderly Affairs.

2. Department of Health.

3. Department of Children and Family Services.

4. Department of Veterans' Affairs.

5. Department of Community Affairs.

6. Agency for Health Care Administration.

7. Agency for Persons with Disabilities.

(3) REIMBURSEMENT TO HEALTH CARE PRACTITIONERS AND FACILITIES.--

(a) The Department of Health shall upon request reimburse~~, subject to the availability of funds for this purpose,~~ health care practitioners, as defined in s. 456.001, provided the practitioner is not providing care to a patient under an existing contract, and emergency medical technicians and paramedics licensed under ~~pursuant to~~ chapter 401, for medical care provided at the request of the department in special needs shelters or at other locations during times of emergency or a declared ~~major~~ disaster. Reimbursement for health care practitioners, except for physicians licensed under ~~pursuant to~~ chapter 458 or chapter 459, shall be based on the average hourly rate that such practitioners were paid according to the most recent survey of Florida hospitals conducted by the Florida Hospital Association or other nationally or state recognized data source. Reimbursement shall be requested on forms prepared by the Department of Health and shall be paid as specified in

paragraph (d).

(b) Hospitals, nursing homes, assisted living facilities, and hospices that are used to shelter special needs persons during or after an evacuation may submit invoices for reimbursement to the department. The department shall develop a form for reimbursement and shall specify by rule which expenses are reimbursable and the rate of reimbursement for each service. Reimbursement for the services described in this paragraph shall be paid as specified in paragraph (d).

(c) If, upon closure of a special needs shelter, a multiagency special needs shelter discharge planning team determines that it is necessary to discharge special needs shelter persons to other health care facilities, such as nursing homes, assisted living facilities, and community residential group homes, the receiving facilities shall be eligible for reimbursement for services provided to the individuals for up to 90 days. Any facility eligible for reimbursement under this paragraph shall submit invoices for reimbursement on forms developed by the department. A facility must show proof of a written request from a representative of an agency serving on the multiagency special needs shelter discharge planning team that the individual for whom the facility is seeking reimbursement for services rendered was referred to that facility from a special needs shelter. Reimbursement for the services described in this paragraph shall be paid as specified in paragraph (d).

(d) If a Presidential Disaster Declaration has been issued ~~made~~, and the Federal Government makes funds available, the

department shall use those ~~such~~ funds for reimbursement of eligible expenditures. In other situations, or if federal funds do not fully compensate the department for reimbursements permissible under ~~reimbursement made pursuant to~~ this section, the department shall process a budget amendment to obtain reimbursement from unobligated, unappropriated moneys in the General Revenue Fund. The department shall not provide reimbursement to facilities under this subsection for services provided to a special needs person if, during the period of time in which the services were provided, the individual was enrolled in another state-funded program such as Medicaid or another similar program; or entities providing health insurance as defined in s. 624.603 or health maintenance organizations or prepaid health clinics as defined in chapter 641, which would otherwise pay for the same services. Travel expense and per diem costs shall be reimbursed pursuant to s. 112.061.

(4) HEALTH CARE PRACTITIONER REGISTRY.--The department may use the registries established in ss. 401.273 and 456.38 when health care practitioners are needed to staff special needs shelters or to assist with other disaster related activities.

(5) SPECIAL NEEDS SHELTER INTERAGENCY COMMITTEE.--The Secretary ~~Department~~ of Health may establish a special needs shelter interagency committee and serve as or appoint a designee to serve as the committee's chair. The department shall provide any necessary staff and resources to support the committee in the performance of its duties~~, to be chaired and staffed by the department~~. The committee shall address and resolve problems related to special needs shelters not addressed in the state

comprehensive emergency medical plan and shall consult on ~~serve as an oversight committee to monitor~~ the planning and operation of special needs shelters.

(a) The committee shall ~~may~~:

1. Develop, negotiate and regularly review any necessary interagency agreements.

2. Undertake other such activities as the department deems necessary to facilitate the implementation of this section.

3. Submit recommendations to the Legislature as necessary.

(b) The special needs shelter interagency committee shall be composed of representatives of emergency management, health, medical, and social services organizations. Membership shall include, but shall not be limited to, representatives of the Departments of Health, Community Affairs, Children and Family Services, Elderly Affairs, ~~Labor and Employment Security,~~ and Education; the Agency for Health Care Administration; the Florida Medical Association; the Florida Osteopathic Medical Association; Associated Home Health Industries of Florida, Inc.; the Florida Nurses Association; the Florida Health Care Association; the Florida Assisted Living Affiliation ~~Association~~; the Florida Hospital Association; the Florida Statutory Teaching Hospital Council; the Florida Association of Homes for the Aging; the Florida Emergency Preparedness Association; the American Red Cross; Florida Hospices and Palliative Care, Inc.; Florida Association of Health Plans, Florida Hospital Association, Private Care Association; ~~and~~ the Salvation Army; the Florida Association of Aging Services Providers; the American Association of Retired Persons (AARP)

and the Florida Renal Coalition.

(c) Meetings of the committee shall be held in Tallahassee, and members of the committee shall serve at the expense of the agencies or organizations they represent. The committee shall make every effort to use teleconference or video conference capabilities in order to ensure statewide input and participation.

(6) RULES.--The department has the authority to adopt rules necessary to implement this section. Rules shall ~~may~~ include:

(a) The definition of a special needs person ~~patient~~, including eligibility criteria for individuals with physical, mental, cognitive impairment or sensory disabilities and the services a special needs person can expect to receive.

(b) The process for special needs shelter health care practitioner and facility reimbursement for services provided in a disaster event.

(c) Guidelines for special needs shelter staffing levels to provide services.

(d) The definition of and standards for special needs shelter supplies and equipment.

(e) Compliance with applicable service animal laws.

(f) Standards for the special needs shelter registration process including guidelines for addressing the needs of unregistered persons in need of a special needs shelter.

(g) Standards for addressing the needs of families that are eligible for special needs shelter services, including the needs of families with multiple dependents where only one

dependent is eligible for the special needs shelter, and the needs of adults with special needs who are caregivers for individuals without special needs.

(h) The requirement of the county health departments seek the participation of hospitals, nursing homes, assisted living facilities, home health agencies, hospice providers, nurse registries and home medical equipment providers and other health and medical emergency preparedness stakeholders in pre-event planning activities.

(7) ~~REVIEW OF~~ EMERGENCY MANAGEMENT PLANS; CONTINUITY OF CARE.--Each emergency management plan submitted to a county health department by a home health agency pursuant to s. 400.492, by a nurse registry pursuant to s. 400.506, a hospice pursuant to s. 400.610 or a home medical equipment provider pursuant to s. 400.925, shall include how the home health agency, nurse registry, hospice or home medical equipment provider will continue to provide staff or equipment to perform the same type and quantity of services to their patients who evacuate to special needs shelters as was provided to those patients prior to evacuation. The submission of emergency management plans to county health departments by home health agencies pursuant to s. 400.497(8)(c) and (d) and by nurse registries pursuant to s. 400.506(16)(e) and by hospice programs pursuant to s. 400.610(1)(b)and by home medical equipment providers pursuant to s. 400.934(20)(a) is conditional upon the receipt of an appropriation by the department to establish ~~medical services~~ disaster coordinator positions in county health departments unless the secretary of the department and a local

county commission jointly determine to require such plans to be submitted based on a determination that there is a special need to protect public health in the local area during an emergency.

Section 3. Subsections (2) and (4) of section 252.385, Florida Statutes, are amended to read:

252.385 Public shelter space.--

(2)(a) The division shall administer a program to survey existing schools, universities, community colleges, and other state-owned, municipally owned, and county-owned public buildings and any private facility that the owner, in writing, agrees to provide for use as a public hurricane evacuation shelter to identify those that are appropriately designed and located to serve as such shelters. The owners of the facilities must be given the opportunity to participate in the surveys. The Board of Regents, district school boards, community college boards of trustees, and the Department of Education are responsible for coordinating and implementing the survey of public schools, universities, and community colleges with the division or the local emergency management agency.

(b) By January 31 of each even-numbered year, the Division of Emergency Management of the Department of Community Affairs shall prepare and submit a statewide emergency shelter plan to the Governor and the Cabinet for approval, subject to the requirements for approval provided in s. 1013.37(2). The plan must also identify the general location and square footage of special needs shelters, by regional planning council region, during the next 5 years. The Department of Health shall assist the division in determining the estimated need for special needs

shelter space and the adequacy of the facility to meet the needs of special needs persons, based on information from the special needs registration and other information.

(4)(a) Public facilities, including schools, postsecondary education facilities, and other facilities owned or leased by the state or local governments, but excluding hospitals, hospice care facilities, assisted living facilities, or nursing homes, which are suitable for use as public hurricane evacuation shelters shall be made available at the request of the local emergency management agencies. The local emergency management agency shall inspect a designated facility to determine its readiness prior to activating such facility for a specific hurricane or disaster. Such agencies shall coordinate with the appropriate school board, university, community college, or local governing board when requesting the use of such facilities as public hurricane evacuation shelters.

(b) The Department of Management Services shall incorporate provisions for the use of suitable leased public facilities as public hurricane evacuation shelters into lease agreements for state agencies. Suitable leased public facilities include leased public facilities that are solely occupied by state agencies and have at least 2,000 square feet of net floor area in a single room or in a combination of rooms having a minimum of 400 square feet in each room. The net square footage of floor area must be determined by subtracting from the gross square footage the square footage of spaces such as mechanical and electrical rooms, storage rooms, open corridors, restrooms, kitchens, science or computer laboratories, shop or mechanical

areas, administrative offices, records vaults, and crawl spaces.

(c) The Department of Management Services shall, in consultation with local and state emergency management agencies, assess Department of Management Services facilities to identify the extent to which each facility has public hurricane evacuation shelter space. The Department of Management Services shall submit proposed facility retrofit projects that incorporate hurricane protection enhancements to the department for assessment and inclusion in the annual report prepared in accordance with subsection (3).

Section 5. Section 400.492, Florida Statutes, is amended to read:

400.492 Provision of services during an emergency.--Each home health agency shall prepare and maintain a comprehensive emergency management plan that is consistent with the standards adopted by national or state accreditation organizations and consistent with the local special needs plan. The plan shall be updated annually and shall provide for continuing home health, services during an emergency that interrupts patient care or services in the patient's home. The plan shall include how the home health agency will continue to provide staff to perform the same type and quantity of services to their patients who evacuate to special needs shelters as staff were providing to those patients prior to evacuation. The plan shall describe how the home health agency establishes and maintains an effective response to emergencies and disasters, including: notifying staff when emergency response measures are initiated; providing for communication between staff members, county health

departments, and local emergency management agencies, including a backup system; identifying resources necessary to continue essential care or services or referrals to other organizations subject to written agreement; and prioritizing and contacting patients who need continued care or services.

(1) Each patient record for patients who are listed in the registry established pursuant to s. 252.355 shall include a description of how care or services will be continued in the event of an emergency or disaster. The home health agency shall discuss the emergency provisions with the patient and the patient's caregivers, including where and how the patient is to evacuate, procedures for notifying the home health agency in the event that the patient evacuates to a location other than the shelter identified in the patient record, and a list of medications and equipment which must either accompany the patient or will be needed by the patient in the event of an evacuation.

(2) Each home health agency shall maintain a current prioritized list of patients who need continued services during an emergency. The list shall indicate how services shall be continued in the event of an emergency or disaster for each patient and if the patient is to be transported to a special needs shelter, and shall indicate if the patient is receiving skilled nursing services and the patient's medication and equipment needs. The list shall be furnished to county health departments and to local emergency management agencies, upon request.

(3) Home health agencies shall not be required to continue

to provide care to patients in emergency situations that are beyond their control and that make it impossible to provide services, such as when roads are impassable or when patients do not go to the location specified in their patient records. Home health agencies may establish links to local emergency operations centers to determine a mechanism to approach areas within the disaster area in order for the agency to reach its clients. The presentation of home care clients to a special needs shelter without the home health agency making a good faith effort to provide services in the shelter setting will constitute abandonment of the client and shall constitute a Class II deficiency, subject to sanctions provided in section 400.484 (2) (b) Florida Statutes.

(4) Notwithstanding the provisions of s. 400.464(2) or any other provision of law to the contrary, a home health agency may provide services in a special needs shelter located in any county.

Section 6. Subsection (8) of section 400.497, Florida Statutes, is amended to read:

400.497 Rules establishing minimum standards.--The agency shall adopt, publish, and enforce rules to implement this part, including, as applicable, ss. 400.506 and 400.509, which must provide reasonable and fair minimum standards relating to:

(8) Preparation of a comprehensive emergency management plan pursuant to s. 400.492.

(c) The plan is subject to review and approval by the county health department. During its review, the county health department shall contact state and local health and medical

stakeholders during its review when necessary. ~~ensure that the following agencies, at a minimum, are given the opportunity to review the plan:~~

~~1. The local emergency management agency.~~

~~2. The Agency for Health Care Administration.~~

~~3. The local chapter of the American Red Cross or other lead sheltering agency.~~

~~4. The district office of the Department of Children and Family Services.~~

The county health department shall complete its review to ensure that the plan is in accordance with the criteria set in the Agency for Health Care Administration rule within 90 days after receipt of the plan and shall either approve the plan or advise the home health agency of necessary revisions.

If the home health agency fails to submit a plan or fails to submit the requested information or revisions to the county health department within 30 days after written notification from the county health department, the county health department shall notify the Agency for Health Care Administration. The agency shall notify the home health agency that such failure constitutes a deficiency, subject to a fine of $5,000 per occurrence. If the plan is not submitted, information is not provided or revisions are not made as requested, the agency may impose the fine.

(d) For any home health agency that operates in more than one county, the Department of Health shall review the plan, after consulting with state and local health and medical stakeholders, when necessary ~~all of the county health~~

~~departments, the agency, and all the local chapters of the American Red Cross or other lead sheltering agencies in the areas of operation for that particular home health agency~~. The Department of Health shall complete its review within 90 days after receipt of the plan and shall either approve the plan or advise the home health agency of necessary revisions. The Department of Health shall make every effort to avoid imposing differing requirements based on differences between counties on the home health agency.

Section 7. Paragraph (a) of subsection (16) of section 400.506, Florida Statutes, is amended to read:

400.506 Licensure of nurse registries; requirements; penalties.--

(16) Each nurse registry shall prepare and maintain a comprehensive emergency management plan that is consistent with the criteria in this subsection and with the local special needs plan. The plan shall be updated annually. The plan shall include how the nurse registry will continue to provide staff to perform the same type and quantity of services to their patients who evacuate to special needs shelters as staff were providing to those patients prior to evacuation. The plan shall specify how the nurse registry shall facilitate the provision of continuous care by persons referred for contract to persons who are registered pursuant to s. 252.355 during an emergency that interrupts the provision of care or services in private residencies. Nurse registries may establish links to local emergency operations centers to determine a mechanism to approach areas within the disaster area in order for the

provider to reach its clients. The presentation of nurse registry clients to a special needs shelter without the nurse registry provider making a good faith effort to provide services in the shelter setting will constitute a Class II deficienty subject to sanctions provided in s. 400.484 (2) (b), F.S..

(e) The comprehensive emergency management plan required by this subsection is subject to review and approval by the county health department. During its review, the county health department shall contact state and local health and medical stakeholders during its review, when necessary ~~ensure that, at a minimum, the local emergency management agency, the Agency for Health Care Administration, and the local chapter of the American Red Cross or other lead sheltering agency are given the opportunity to review the plan.~~ ~~T~~The county health department shall complete its review to ensure that the plan is in accordance with the criteria set in the Agency for Health Care Administration rule within 90 days after receipt of the plan and shall either approve the plan or advise the nurse registry of necessary revisions.

If a nurse registry fails to submit a plan or fails to submit requested information or revisions to the county health department with 30 days after written notification from the county health department, the county health department shall notify the Agency for Health Care Administration. The agency shall notify the nurse registry that such failure constitutes a deficiency, subject to a fine of $5,000 per occurrence. If the plan is not submitted, information is not provided, or revisions are not made as requested, the agency may impose the fine.

(f) For any nurse registry that operates in more than one county, the Department of Health shall review the plan. The Department of Health shall make every effort to avoid imposing differing requirements based on differences between counties on the nurse registry.

Section 8. Paragraphs (a) and (b) of subsection (1) of section 400.610, Florida Statutes, are amended to read:

400.610 Administration and management of a hospice.--

(1) A hospice shall have a clearly defined organized governing body, consisting of a minimum of seven persons who are representative of the general population of the community served. The governing body shall have autonomous authority and responsibility for the operation of the hospice and shall meet at least quarterly. The governing body shall:

(b)1. Prepare and maintain a comprehensive emergency management plan that provides for continuing hospice services in the event of an emergency that is consistent with local special needs plans. The plan shall include provisions for ensuring continuing care to hospice patients who go to special needs shelters. The plan shall include how the hospice provider will continue to provide staff to perform the same type and quantity of services to their patients who evacuate to special needs shelters as staff were providing to those patients prior to evacuation. The plan is subject to review and approval by the county health department, except as provided in subparagraph 2. During its review, the county health department shall contact state and local health and medical stakeholders, when necessary ~~ensure that the department, the agency, and the local chapter of~~

~~the American Red Cross or other lead sheltering agency have an opportunity to review and comment on the plan~~. The county health department shall complete its review to ensure that the plan is in accordance with the criteria set in the Department of Elderly Affairs rule within 90 days after receipt of the plan and shall either approve the plan or advise the hospice of necessary revisions. Hospice providers may establish links to local emergency operations centers to determine a mechanism to approach areas within the disaster area in order for the provider to reach its clients. The presentation of hospice clients to a special needs shelter without the hospice provider making a good faith effort to provide services in the shelter setting will constitute abandonment of the client.

2. For any hospice that operates in more than one county, the Department of Health during its ~~shall~~ review shall contact state and local health and medical stakeholders, when necessary ~~the plan, after consulting with all of the county health departments, the agency, and all the local chapters of the American Red Cross or other lead sheltering agency in the areas of operation for that particular hospice~~. The Department of Health shall complete its review to ensure that the plan is in accordance with the criteria set in the Department of Elderly Affairs rule within 90 days after receipt of the plan and shall either approve the plan or advise the hospice of necessary revisions. The Department of Health shall make every effort to avoid imposing on the hospice differing requirements based on differences between counties.

Section 9. Subsection (13), subsection (15), and

subsection (16) of section 400.925, Florida Statutes, are amended to read:

400.925 Definitions.--As used in this part, the term:

(13) Life-supporting or life-sustaining equipment means a device that is essential to or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life. Life-supporting or life-sustaining equipment includes apnea monitors, enteral feeding pumps, infusion pumps, portable home dialysis equipment, and ventilator equipment and supplies for all related equipment, including oxygen equipment and related respiratory equipment.

Section 10. Section 400.934, Florida Statutes, is amended to read:

400.934 Minimum standards.--As a requirement of licensure, home medical equipment providers shall:

(20) Prepare and maintain a comprehensive emergency management plan that meets minimum criteria established by the agency in rule pursuant to 400.935, F.S. The plan shall be updated annually and shall provide for continuing home medical equipment services for life-supporting or life-sustaining equipment, as defined in 400.925, F.S., during an emergency that interrupts home medical equipment services in the patient's home. The plan shall include how the home medical equipment provider will continue to provide equipment to perform the same type and quantity of services to their patients who evacuate to special needs shelters as staff were providing to those patients prior to evacuation. The plan shall describe how the home

medical provider establishes and maintains an effective response to emergencies and disasters, including: notifying staff when emergency response measures are initiated; providing for communication between staff members, county health departments, and local emergency management agencies, including a backup system; identifying resources necessary to continue essential care or services or referrals to other organizations subject to written agreement; and prioritizing and contacting consumers who need continued medical equipment services and supplies.

(a) The plan is subject to review and approval by the county health department. During its review, the county health department shall contact state and local health and medical stakeholders, when necessary. The county health department shall complete its review to ensure that the plan is in accordance with the criteria set in the Agency for Health Care Administration rule within 90 days after receipt of the plan.

If a home medical equipment provider fails to submit a plan or fails to submit requested information or revisions to the county health department within 30 days after written notification from the county health department, the county health department shall notify the Agency for Health Care Administration. The agency shall notify the home medical equipment provider that such failure constitutes a deficiency, subject to a fine of $5,000 per occurrence. If the plan is not submitted, information is not provided, or revisions are not made as requested, the agency may impose the fine.

(b) For any home medical equipment provider that operates in more than one county, the Department of Health shall review

the plan. The Department of Health shall make every effort to avoid imposing differing requirements based on differences between counties on the home medical equipment provider.

(1) Each home medical equipment provider shall maintain a current prioritized list of patients who needs continued services during an emergency. The list shall indicate how services shall be continued in the event of an emergency or disaster for each consumer and if the consumer is to be transported to a special needs shelter, and shall indicate if the consumer has life-supporting or life-sustaining equipment, including the specific type of equipment and related supplies. The list shall be furnished to county health departments and to local emergency management agencies, upon request.

(2) Home medical equipment providers may establish links to local emergency operations centers to determine a mechanism to approach areas within the disaster in order for the provider to reach its patients.

Section 11. Section 400.935, Florida Statutes, is amended to read:

400.935 Rules establishing minimum standards.--The agency shall adopt, publish, and enforce rules to implement this part, which must provide reasonable and fair minimum standards relating to:

(10) Home medical equipment requiring home medical equipment services.

(11) Preparation of a comprehensive emergency management plan pursuant to s. 400.934.

(a) The Agency for Health Care Administration shall adopt

rules establishing minimum criteria for the plan, including maintaining patient equipment and supply lists that can accompany patients who are transported from their homes, in consultation with the Department of Health and the Department of Community Affairs.

Section 12. Section 408.831, Florida Statutes, is amended to read:

408.831 Denial, suspension, or revocation of a license, registration, certificate, or application.--

(1) In addition to any other remedies provided by law, the agency may deny each application or suspend or revoke each license, registration, or certificate of entities regulated or licensed by it:

(a) If the applicant, licensee, registrant, or certificate holder, or, in the case of a corporation, partnership, or other business entity, if any officer, director, agent, or managing employee of that business entity or any affiliated person, partner, or shareholder having an ownership interest equal to 5 percent or greater in that business entity, has failed to pay all outstanding fines, liens, or overpayments assessed by final order of the agency or final order of the Centers for Medicare and Medicaid Services, not subject to further appeal, unless a repayment plan is approved by the agency; or

(b) For failure to comply with any repayment plan.

(2) In reviewing any application requesting a change of ownership or change of the licensee, registrant, or certificateholder, the transferor shall, prior to agency approval of the change, repay or make arrangements to repay any

amounts owed to the agency. Should the transferor fail to repay or make arrangements to repay the amounts owed to the agency, the issuance of a license, registration, or certificate to the transferee shall be delayed until repayment or until arrangements for repayment are made.

(3) Entities subject to this section may exceed their licensed capacity to act as a receiving facility in accordance with an emergency operations plan for clients of evacuating providers from a geographic area where an evacuation order has been issued by a local authority having jurisdiction. While in an overcapacity status, each provider must furnish or arrange for appropriate care and services to all clients. In addition, the agency may approve requests for overcapacity beyond 15 days, which approvals shall be based upon satisfactory justification and need as provided by the receiving and sending facility.

(4) An inactive license may be issued to a licensee subject to this section when the provider is located in a geographic area where a state of emergency was declared by the Governor of Florida if the provider:

(a) Suffered damage to the provider's operation during that state of emergency.

(b) Is currently licensed.

(c) Does not have a provisional license.

(d) Will be temporarily unable to provide services but is reasonably expected to resume services within 12 months.

An inactive license may be issued for a period not to exceed 12 months but may be renewed by the agency for up to 12 additional

months upon demonstration to the agency of progress toward reopening. A request by a licensee for an inactive license or to extend the previously approved inactive period must be submitted in writing to the agency, accompanied by written justification for the inactive license which states the beginning and ending dates of inactivity and includes a plan for the transfer of any clients to other providers and appropriate licensure fees. Upon agency approval, the licensee shall notify clients of any necessary discharge or transfer as required by authorizing statutes or applicable rules. The beginning of the inactive licensure period shall be the date the provider ceases operations. The end of the inactive period shall become the licensee expiration date and all licensure fees must be current, paid in full, and may be prorated. Reactivation of an inactive license requires the prior approval by the agency of a renewal application, including payment of licensure fees and agency inspections indicating compliance with all requirements of this part and applicable rules and statutes.

(5) ~~(3)~~ This section provides standards of enforcement applicable to all entities licensed or regulated by the Agency for Health Care Administration. This section controls over any conflicting provisions of chapters 39, 381, 383, 390, 391, 393, 394, 395, 400, 408, 468, 483, and 641 or rules adopted pursuant to those chapters.

Section 14. Section 252.357, Florida Statutes, is created to read:

252.357 Monitoring of nursing homes during disaster.--The Florida Comprehensive Emergency Management Plan shall permit the

Agency for Health Care Administration, working from the agency's offices or in the Emergency Operations Center, ESF-8, to make initial contact with each nursing home in the disaster area. The agency, by July 15, 2006, and annually thereafter, shall publish on the Internet an emergency telephone number that can be used by nursing homes to contact the agency on a schedule established by the agency to report requests for assistance. The agency may also provide the telephone number to each facility when it makes the initial facility call.

Section 15. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 01(for drafter's use only)

Bill No. **PCB HCG 06-01**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care General

Representative(s) Harrell offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 252.355, Florida Statutes, is amended to read:

252.355 Registry of persons with special needs; notice.--

(1) In order to meet the special needs of persons who would need assistance during evacuations and sheltering because of physical, mental, cognitive impairment, or sensory disabilities, each local emergency management agency in the state shall maintain a registry of persons with special needs located within the jurisdiction of the local agency. The registration shall identify those persons in need of assistance and plan for resource allocation to meet those identified needs. To assist the local emergency management agency in identifying such persons, home health agencies, hospices, nurse registries, home medical equipment providers, the Department of Children and Family Services, Department of Health, Agency for Health Care Administration, Department of Education, Agency for Persons with Disabilities, ~~Department of Labor and Employment Security,~~ and

Department of Elderly Affairs shall provide registration information to all of their special needs clients and to all people with disabilities or special needs who receive services ~~incoming clients as a part of the intake process~~. The registry shall be maintained year-round ~~updated annually~~. The registration program shall give persons with special needs the option of preauthorizing emergency response personnel to enter their homes during search and rescue operations if necessary to assure their safety and welfare following disasters.

(2) The Department of Community Affairs shall be the designated lead agency responsible for community education and outreach to the general public, including special needs clients, regarding registration and special needs shelters and general information regarding shelter stays. The Department of Community Affairs shall disseminate such educational and outreach information through the local emergency management offices. The department shall coordinate the development of curriculum and dissemination of all community education and outreach related to special needs shelters with the Clearinghouse on Disability Information of the Governor's Working Group on the Americans with Disabilities Act, the Department of Children and Family Services, the Department of Health, the Agency for Health Care Administration, the Department of Education, the Agency for Persons with Disabilities, and the Department of Elderly Affairs. The special needs shelter is considered a public facility when it is activated for a disaster. Under the Americans with Disabilities Act (ADA), Public Law 101.336, businesses and organizations that serve the public must allow people with disabilities to bring their service animals into all areas of the facility where customers are normally allowed to go.

~~(2) On or before May 1 of each year each electric utility in the state shall annually notify residential customers in its service area of the availability of the registration program available through their local emergency management agency.~~

(3) Each electric utility in the state shall notify residential customers in its service area of the availability of the registration program available through their local emergency management agency in either of the following ways:

(a) Upon the initiation of new residential service with the electric utility, and one time for all residential customers between January 1 and May 31 of each year, or

(b) Two times for all residential customers between January 1 and May 31 of each year.

The notification required above may be made by any available means including but not limited to written, electronic or verbal notification. The notification may be made concurrently with any other notification to residential customers required by law or rule.

(4)~~(3)~~ All records, data, information, correspondence, and communications relating to the registration of persons with special needs as provided in subsection (1) are confidential and exempt from the provisions of s. 119.07(1), except that such information shall be available to other emergency response agencies, as determined by the local emergency management director, and to the Department of Health in the furtherance of its duties and responsibilities.

(5)~~(4)~~ All appropriate agencies and community-based service providers, including home health care providers, ~~and~~ hospices, nurse registries, and home medical equipment providers, shall assist emergency management agencies by

collecting registration information for persons with special needs as part of program intake processes, establishing programs to increase the awareness of the registration process, and educating clients about the procedures that may be necessary for their safety during disasters. Clients of state or federally funded service programs with physical, mental, cognitive impairment, or sensory disabilities who need assistance in evacuating, or when in shelters, must register as persons with special needs.

Section 2. Section 252.3568, Florida Statutes, is created to read:

252.3568 Emergency sheltering of persons with pets.--

(1) GENERAL PROVISIONS.--In accordance with the provisions of s. 252.35, the division shall address evacuation of persons with pets in the shelter component of the state comprehensive emergency management plan. The Department of Agriculture and Consumer Services shall assist the division in determining strategies regarding this activity.

Section 3. Section 252.357, Florida Statutes, is created to read:

252.357 Monitoring of nursing homes during disaster.--The Florida Comprehensive Emergency Management Plan shall permit the Agency for Health Care Administration, working from the agency's offices or in the Emergency Operations Center, ESF-8, to make initial contact with each nursing home in the disaster area. The agency, by July 15, 2006, and annually thereafter, shall publish on the Internet an emergency telephone number that may be used by nursing homes to contact the agency on a schedule established by the agency to report requests for assistance. The agency may also provide the telephone number to each facility when it makes the initial facility call.

Section 4. Subsections (2) and (4) of section 252.385, Florida Statutes, are amended to read:

252.385 Public shelter space.--

(2)(a) The division shall administer a program to survey existing schools, universities, community colleges, and other state-owned, municipally owned, and county-owned public buildings and any private facility that the owner, in writing, agrees to provide for use as a public hurricane evacuation shelter to identify those that are appropriately designed and located to serve as such shelters. The owners of the facilities must be given the opportunity to participate in the surveys. The Board of Regents, district school boards, community college boards of trustees, and the Department of Education are responsible for coordinating and implementing the survey of public schools, universities, and community colleges with the division or the local emergency management agency.

(b) By January 31 of each even-numbered year, the Division of Emergency Management of the Department of Community Affairs shall prepare and submit a statewide emergency shelter plan to the Governor and the Cabinet for approval, subject to the requirements for approval provided in s. 1013.37(2). The plan shall also identify the general location and square footage of special needs shelters, by regional planning council region, during the next 5 years. The Department of Health shall assist the division in determining the estimated need for special needs shelter space and the adequacy of the facility to meet the needs of special needs persons, based on information from the special needs registration and other information.

(c) The division shall include information on the availability of pet friendly shelters in the statewide emergency shelter plan.

(4)(a) Public facilities, including schools, postsecondary education facilities, and other facilities owned or leased by the state or local governments, but excluding hospitals, hospice care facilities, assisted living facilities, or nursing homes, which are suitable for use as public hurricane evacuation shelters shall be made available at the request of the local emergency management agencies. The local emergency management agency shall inspect a designated facility to determine its readiness prior to activating such facility for a specific hurricane or disaster. Such agencies shall coordinate with the appropriate school board, university, community college, or local governing board when requesting the use of such facilities as public hurricane evacuation shelters.

(b) The Department of Management Services shall incorporate provisions for the use of suitable leased public facilities as public hurricane evacuation shelters into lease agreements for state agencies. Suitable leased public facilities include leased public facilities that are solely occupied by state agencies and have at least 2,000 square feet of net floor area in a single room or in a combination of rooms having a minimum of 400 square feet in each room. The net square footage of floor area ~~must~~ shall be determined by subtracting from the gross square footage the square footage of spaces such as mechanical and electrical rooms, storage rooms, open corridors, restrooms, kitchens, science or computer laboratories, shop or mechanical areas, administrative offices, records vaults, and crawl spaces.

(c) The Department of Management Services shall, in consultation with local and state emergency management agencies assess the Department of Management Services facilities to identify the extent to which each facility has public hurricane

evacuation shelter space. The Department of Management Services shall submit proposed facility retrofit projects that incorporate hurricane protection enhancements to the department for assessment and inclusion in the annual report prepared in accordance with subsection (3).

Section 5. Section 381.0303, Florida Statutes, is amended to read:

381.0303 ~~Health practitioner recruitment for~~ Special needs shelters.--

(1) PURPOSE.--The purpose of this section is to provide for the operation, maintenance, and closure of special needs shelters and to designate the Department of Health, through its county health departments, as the lead agency for coordination of the recruitment of health care practitioners, as defined in s. 456.001(4), to staff special needs shelters in times of emergency or disaster and to provide resources to the department to carry out this responsibility. However, nothing in this section prohibits a county health department from entering into an agreement with a local emergency management agency to assume the lead responsibility for recruiting health care practitioners.

(2) SPECIAL NEEDS SHELTER PLAN; STAFFING; CLOSURE; STATE AGENCY ASSISTANCE ~~AND STAFFING~~.--Provided funds have been appropriated to support ~~medical services~~ disaster coordinator positions in county health departments~~,~~:

(a) The department shall assume lead responsibility for the ~~local~~ coordination of local medical and health care providers, the American Red Cross, and other interested parties in developing a plan for the staffing and medical management of special needs shelters. The local Children's Medical Services offices shall assume lead responsibility for the coordination of

local medical and health care providers, the American Red Cross, and other interested parties in developing a plan for the staffing and medical management of pediatric special needs shelters. Plans shall conform to ~~The plan shall be in conformance with~~ the local comprehensive emergency management plan.

(b) ~~(a)~~ County health departments shall, in conjunction with the local emergency management agencies, have the lead responsibility for coordination of the recruitment of health care practitioners to staff local special needs shelters. County health departments shall assign their employees to work in special needs shelters when those employees are needed to protect the health and safety of special needs persons ~~of patients~~. County governments shall assist the Department of Health with non-medical staffing and operating of special needs shelters. The local health department and emergency management agency shall coordinate these efforts to ensure appropriate staffing in special needs shelters.

(c) ~~(b)~~ The appropriate county health department, Children's Medical Services office, and local emergency management agency shall jointly decide ~~determine~~ who has responsibility for medical supervision in each ~~a~~ special needs shelter and shall notify the department of Community Affairs Division of Emergency Management and the Department of Health of their decision.

(d) ~~(c)~~ Local emergency management agencies shall be responsible for the designation, ~~and~~ operation, and infrastructure of special needs shelters during times of emergency or disaster and the closure of the facilities following an emergency or disaster. The emergency management agency and the local health department shall coordinate these

efforts to ensure appropriate designation, operation and infrastructure in special needs shelters. County health departments shall assist the local emergency management agency with regard to the management of medical services in special needs shelters. However, nothing in this section prohibits a county health department from entering into an alternative agreement with a local emergency management agency to assume the lead responsibility for special needs shelter supplies and equipment.

(e) State employees with a pre-established role provided by the employee's respective agency in disaster response unless they have other mandated response activities that preclude participation, are subject to serve in times of disaster commensurate with their knowledge, skills, and abilities and any needed activities related to the situation.

(f) The Secretary of Elderly Affairs, or his or her designee, shall convene, at any time that he or she deems appropriate and necessary, a multiagency special needs shelter discharge planning team or teams to assist local areas that are severely impacted by a natural or manmade disaster that requires the use of special needs shelters. Multiagency special needs shelter discharge planning teams shall provide assistance to local emergency management agencies with the continued operation or closure of the shelters, as well as with the discharge of special needs clients to alternate facilities if necessary. Local emergency management agencies may request the assistance of a multiagency special needs shelter discharge planning team by alerting statewide emergency management officials of the necessity for additional assistance in their area. The Secretary of Elderly Affairs is encouraged to proactively work with other state agencies prior to any natural disasters for which warnings

are provided to ensure that multiagency special needs shelter discharge planning teams are ready to assemble and deploy rapidly upon a determination by state emergency management officials that a disaster area requires additional assistance. The Secretary of Elderly Affairs may call upon any state agency or office to provide staff to assist a multiagency special needs shelter discharge planning team or teams. Unless the secretary determines that the nature or circumstances surrounding the disaster do not warrant participation from a particular agency's staff, each multiagency special needs shelter discharge planning team shall include at least one representative from each of the following state agencies:

1. Department of Elderly Affairs.
2. Department of Health.
3. Department of Children and Family Services.
4. Department of Veterans' Affairs.
5. Department of Community Affairs.
6. Agency for Health Care Administration.
7. Agency for Persons with Disabilities.

(3) REIMBURSEMENT TO HEALTH CARE PRACTITIONERS AND FACILITIES.--

(a) The Department of Health shall upon request reimburse~~,~~ ~~subject to the availability of funds for this purpose,~~ health care practitioners, as defined in s. 456.001, provided the practitioner is not providing care to a patient under an existing contract, and emergency medical technicians and paramedics licensed under ~~pursuant to~~ chapter 401, for medical care provided at the request of the department in special needs shelters or at other locations during times of emergency or a declared ~~major~~ disaster. Reimbursement for health care practitioners, except for physicians licensed under ~~pursuant to~~

chapter 458 or chapter 459, shall be based on the average hourly rate that such practitioners were paid according to the most recent survey of Florida hospitals conducted by the Florida Hospital Association or other nationally or state recognized data source. Reimbursement shall be requested on forms prepared by the Department of Health and shall be paid as specified in paragraph (c).

(b) If, upon closure of a special needs shelter, a multiagency special needs shelter discharge planning team determines that it is necessary to discharge special needs persons to other health care facilities, such as hospitals, nursing homes, assisted living facilities, and community residential homes, the receiving facilities shall be eligible for reimbursement for services provided to the individuals for up to 90 days. Any facility eligible for reimbursement under this paragraph shall submit invoices for reimbursement on forms developed by the department. A facility must show proof of a written request from a representative of an agency serving on the multiagency special needs shelter discharge planning team that the individual for whom the facility is seeking reimbursement for services rendered was referred to that facility from a special needs shelter. The department shall specify by rule which expenses are reimbursable and the rate of reimbursement for each service. Reimbursement for the services described in this paragraph shall be paid as specified in paragraph (c).

(c) If a Presidential Disaster Declaration has been issued ~~made, and the Federal Government makes funds available~~, the department shall request federal ~~use such funds for~~ reimbursement of eligible expenditures. In other situations, or if federal funds do not fully compensate the department for

reimbursements permissible under ~~reimbursement made pursuant to~~ this section, the department shall process a budget amendment to obtain reimbursement from unobligated, unappropriated moneys in the General Revenue Fund. The department shall not provide reimbursement to facilities under this subsection for services provided to a special needs person if, during the period of time in which the services were provided, the individual was enrolled in another state-funded program, such as Medicaid or another similar program, or entities providing health insurance as defined in s. 624.603 or health maintenance organizations or prepaid health clinics as defined in chapter 641, which would otherwise pay for the same services. Travel expense and per diem costs shall be reimbursed pursuant to s. 112.061.

(4) HEALTH CARE PRACTITIONER REGISTRY.--The department may use the registries established in ss. 401.273 and 456.38 when health care practitioners are needed to staff special needs shelters or to assist with other disaster related activities ~~staff disaster medical assistance teams~~.

(5) SPECIAL NEEDS SHELTER INTERAGENCY COMMITTEE.--The Secretary ~~Department~~ of Health may establish a special needs shelter interagency committee and serve as or appoint a designee to serve as the committee's chair. The department shall provide any necessary staff and resources to support the committee in the performance of its duties~~, to be chaired and staffed by the department~~. The committee shall address and resolve problems related to special needs shelters not addressed in the state comprehensive emergency medical plan and shall consult on ~~serve as an oversight committee to monitor~~ the planning and operation of special needs shelters.

(a) The committee shall ~~may~~:

1. Develop, ~~and~~ negotiate and regularly review any necessary interagency agreements.

2. Undertake other such activities as the department deems necessary to facilitate the implementation of this section.

3. Submit recommendations to the Legislature as necessary.

(b) The special needs shelter interagency committee shall be composed of representatives of emergency management, health, medical, and social services organizations. Membership shall include, but shall not be limited to, representatives of the Departments of Health, Community Affairs, Children and Family Services, Elderly Affairs, ~~Labor and Employment Security,~~ and Education; the Agency for Health Care Administration; the Florida Medical Association; the Florida Osteopathic Medical Association; Associated Home Health Industries of Florida, Inc.; the Florida Nurses Association; the Florida Health Care Association; the Florida Assisted Living Affiliation ~~Association~~; the Florida Hospital Association; the Florida Statutory Teaching Hospital Council; the Florida Association of Homes for the Aging; the Florida Emergency Preparedness Association; the American Red Cross; Florida Hospices and Palliative Care, Inc.; the Association of Community Hospitals and Health Systems; the Florida Association of Health Maintenance Organizations; the Florida League of Health Systems; Private Care Association; ~~and~~ the Salvation Army; the Florida Association of Aging Services Providers; AARP, and the Florida Renal Coalition.

(c) Meetings of the committee shall be held in Tallahassee, and members of the committee shall serve at the expense of the agencies or organizations they represent. The committee shall make every effort to use teleconference or video

conference capabilities in order to ensure statewide input and participation.

(6) RULES.--The department has the authority to adopt rules necessary to implement this section. Rules shall ~~may~~ include:

(a) The ~~a~~ definition of a special needs person, including eligibility criteria for individuals with physical, mental, cognitive impairment or sensory disabilities and the services a special needs person can expect to receive in a special needs shelter. ~~patient, specify physician reimbursement, and designate which county health departments will have responsibility for implementation of subsections (2) and (3)~~.

(b) The process for special needs shelter health care practitioner and facility reimbursement for services provided in a disaster event.

(c) Guidelines for special needs shelter staffing levels to provide services.

(d) The definition of and standards for special needs shelter supplies and equipment, including durable medical equipment.

(e) Compliance with applicable service animal laws.

(f) Standards for the special needs shelter registration process including guidelines for addressing the needs of unregistered persons in need of a special needs shelter.

(g) Standards for addressing the needs of families where only one dependent is eligible for the special needs shelter, and the needs of adults with special needs who are caregivers for individuals without special needs.

(h) The requirement of the county health departments to seek the participation of hospitals, nursing homes, assisted living facilities, home health agencies, hospice providers,

nurse registries and home medical equipment providers, dialysis centers, and other health and medical emergency preparedness stakeholders in pre-event planning activities.

(7) ~~REVIEW OF~~ EMERGENCY MANAGEMENT PLANS; CONTINUITY OF CARE.--Each emergency management plan submitted to a county health department by a home health agency pursuant to s. 400.492, by a nurse registry pursuant to s. 400.506, by a hospice pursuant to s. 400.610, or a home medical equipment provider pursuant to s. 400.925, shall specify how the home health agency, nurse registry, hospice or home medical equipment provider will continue to provide staff or equipment to perform the same type and quantity of services to their patients who evacuate to special needs shelters as was provided to those patients prior to evacuation. The submission of Emergency management plans to county health departments by home health agencies pursuant to s. 400.497(8)(c) and (d) and by nurse registries pursuant to s. 400.506(16)(e) and by hospice programs pursuant to s. 400.610(1)(b) and by home medical equipment providers pursuant to s. 400.934(20)(a) is conditional upon the receipt of an appropriation by the department to establish ~~medical services~~ disaster coordinator positions in county health departments unless the secretary of the department and a local county commission jointly determine to require such plans to be submitted based on a determination that there is a special need to protect public health in the local area during an emergency.

Section 6. Section 400.492, Florida Statutes, is amended to read:

400.492 Provision of services during an emergency.--Each home health agency shall prepare and maintain a comprehensive emergency management plan that is consistent with the standards adopted by national or state accreditation organizations and

consistent with the local special needs plan. The plan shall be updated annually and shall provide for continuing home health services during an emergency that interrupts patient care or services in the patient's home. The plan shall include how the home health agency will continue to provide staff to perform the same type and quantity of services to their patients who evacuate to special needs shelters as staff were providing to those patients prior to evacuation. The plan shall describe how the home health agency establishes and maintains an effective response to emergencies and disasters, including: notifying staff when emergency response measures are initiated; providing for communication between staff members, county health departments, and local emergency management agencies, including a backup system; identifying resources necessary to continue essential care or services or referrals to other organizations subject to written agreement; and prioritizing and contacting patients who need continued care or services.

(1) Each patient record for patients who are listed in the registry established pursuant to s. 252.355 shall include a description of how care or services will be continued in the event of an emergency or disaster. The home health agency shall discuss the emergency provisions with the patient and the patient's caregivers, including where and how the patient is to evacuate, procedures for notifying the home health agency in the event that the patient evacuates to a location other than the shelter identified in the patient record, and a list of medications and equipment which must either accompany the patient or will be needed by the patient in the event of an evacuation.

(2) Each home health agency shall maintain a current prioritized list of patients who need continued services during

an emergency. The list shall indicate how services shall be continued in the event of an emergency or disaster for each patient and if the patient is to be transported to a special needs shelter, and shall indicate if the patient is receiving skilled nursing services and the patient's medication and equipment needs. The list shall be furnished to county health departments and to local emergency management agencies, upon request.

(3) Home health agencies shall not be required to continue to provide care to patients in emergency situations that are beyond their control and that make it impossible to provide services, such as when roads are impassable or when patients do not go to the location specified in their patient records. Home health agencies may establish links to local emergency operations centers to determine a mechanism to approach areas within the disaster area in order for the agency to reach its clients. The presentation of a home health agency client to a special needs shelter without the home health agency making a good faith effort to provide services in the shelter setting will constitute abandonment of the client and shall constitute a Class II deficiency, subject to sanctions provided in section 400.484(2)(b) Florida Statutes. For the purposes of this section, "good faith effort" may be demonstrated by documented attempts of staff to follow procedures as outlined in the home health agency's comprehensive emergency management plan and the patient's record, providing continuing care for those patients who have been identified as needing care by the home health agency in the event of an emergency pursuant to s. 400.492(1).

(4) Notwithstanding the provisions of s. 400.464(2) or any other provision of law to the contrary, a home health agency may

provide services in a special needs shelter located in any county.

Section 7. Subsection (8) of section 400.497, Florida Statutes, is amended to read:

400.497 Rules establishing minimum standards.--The agency shall adopt, publish, and enforce rules to implement this part, including, as applicable, ss. 400.506 and 400.509, which ~~must~~ shall provide reasonable and fair minimum standards relating to:

(8) Preparation of a comprehensive emergency management plan pursuant to s. 400.492.

(c) The plan is subject to review and approval by the county health department. During its review, the county health department shall contact state and local health and medical stakeholders during its review when necessary ~~ensure that the following agencies, at a minimum, are given the opportunity to review the plan:~~

~~1. The local emergency management agency.~~

~~2. The Agency for Health Care Administration.~~

~~3. The local chapter of the American Red Cross or other lead sheltering agency.~~

~~4. The district office of the Department of Children and Family Services~~.

The county health department shall complete its review to ensure that the plan is in accordance with the criteria set in the Agency for Health Care Administration rule within 90 ~~60~~ days after receipt of the plan and shall either approve the plan or advise the home health agency of necessary revisions.

If the home health agency fails to submit a plan or fails to submit the requested information or revisions to the county health department within 30 days after written notification from the county health department, the county health department shall

notify the Agency for Health Care Administration. The agency shall notify the home health agency that such failure constitutes a deficiency, subject to a fine of $5,000 per occurrence. If the plan is not submitted, information is not provided or revisions are not made as requested, the agency may impose the fine.

(d) For any home health agency that operates in more than one county, the Department of Health shall review the plan, after consulting with state and local health and medical stakeholders, when necessary ~~all of the county health departments, the agency, and all the local chapters of the American Red Cross or other lead sheltering agencies in the areas of operation for that particular home health agency~~. The Department of Health shall complete its review within 90 days after receipt of the plan and shall either approve the plan or advise the home health agency of necessary revisions. The Department of Health shall make every effort to avoid imposing differing requirements based on differences between counties on the home health agency.

Section 8. Paragraph (a) of subsection (16) of section 400.506, Florida Statutes, is amended to read:

400.506 Licensure of nurse registries; requirements; penalties.--

(16) Each nurse registry shall prepare and maintain a comprehensive emergency management plan that is consistent with the criteria in this subsection and with the local special needs plan. The plan shall be updated annually. The plan shall include how the nurse registry will continue to provide staff to perform the same type and quantity of services to their patients who evacuate to special needs shelters as staff were providing to those patients prior to evacuation. The plan shall specify how

the nurse registry shall facilitate the provision of continuous care by persons referred for contract to persons who are registered pursuant to s. 252.355 during an emergency that interrupts the provision of care or services in private residencies. Nurse registries may establish links to local emergency operations centers to determine a mechanism to approach areas within the disaster area in order for the provider to reach its clients. The presentation of nurse registry clients to a special needs shelter without the nurse registry provider making a good faith effort to provide services in the shelter setting will constitute a Class II deficiency subject to sanctions provided in s. 400.484 (2) (b), F.S. For the purposes of this section, "good faith effort" may be demonstrated by documented attempts of staff to follow procedures as outlined in the nurse registry's comprehensive emergency management plan, providing continuing care for those patients who have been identified as needing care by the nurse registry in the event of an emergency pursuant to s. 400.506(1).

(e) The comprehensive emergency management plan required by this subsection is subject to review and approval by the county health department. During its review, the county health department shall contact state and local health and medical stakeholders, when necessary ~~ensure that, at a minimum, the local emergency management agency, the Agency for Health Care Administration, and the local chapter of the American Red Cross or other lead sheltering agency are given the opportunity to review the plan~~. The county health department shall complete its review to ensure that the plan is in accordance with the criteria set in the Agency for Health Care Administration rule within 90 ~~60~~ days after receipt of the plan and shall either

approve the plan or advise the nurse registry of necessary revisions.

If a nurse registry fails to submit a plan or fails to submit requested information or revisions to the county health department within 30 days after written notification from the county health department, the county health department shall notify the Agency for Health Care Administration. The agency shall notify the nurse registry that such failure constitutes a deficiency, subject to a fine of $5,000 per occurrence. If the plan is not submitted, information is not provided, or revisions are not made as requested, the agency may impose the fine.

(f) For any nurse registry that operates in more than one county, the Department of Health shall review the plan. The Department of Health shall complete its review within 90 days after receipt of the plan and shall either approve the plan or advise the nurse registry of necessary revisions. The Department of Health shall make every effort to avoid imposing differing requirements based on differences between counties on the nurse registry.

Section 9. Paragraphs (a) and (b) of subsection (1) of section 400.610, Florida Statutes, are amended to read:

400.610 Administration and management of a hospice.--

(1) A hospice shall have a clearly defined organized governing body, consisting of a minimum of seven persons who are representative of the general population of the community served. The governing body shall have autonomous authority and responsibility for the operation of the hospice and shall meet at least quarterly. The governing body shall:

(b)1. Prepare and maintain a comprehensive emergency management plan that provides for continuing hospice services in the event of an emergency that is consistent with local special

needs plans. The plan shall include provisions for ensuring continuing care to hospice patients who go to special needs shelters. The plan shall include how the hospice provider will continue to provide staff to perform the same type and quantity of services to their patients who evacuate to special needs shelters as staff were providing to those patients prior to evacuation. The plan is subject to review and approval by the county health department, except as provided in subparagraph 2. During its review, the county health department shall contact state and local health and medical stakeholders, when necessary ~~ensure that the department, the agency, and the local chapter of the American Red Cross or other lead sheltering agency have an opportunity to review and comment on the plan~~. The county health department shall complete its review to ensure that the plan is in accordance with the criteria set in the Department of Elderly Affairs rule within 90 ~~60~~ days after receipt of the plan and shall either approve the plan or advise the hospice of necessary revisions. Hospice providers may establish links to local emergency operations centers to determine a mechanism to approach areas within the disaster area in order for the provider to reach its clients. The presentation of hospice clients to a special needs shelter without the hospice provider making a good faith effort to provide services in the shelter setting will constitute abandonment of the client subject to sanction as provided by law or rule. For the purposes of this section, "good faith effort" may be demonstrated by documented attempts of staff to follow procedures as outlined in the hospice's comprehensive emergency management plan and providing continuing care for those patients who have been identified as needing alternative caregiver services in the event of an emergency.

2. For any hospice that operates in more than one county, the Department of Health during its ~~shall~~ review shall contact state and local health and medical stakeholders, when necessary ~~the plan, after consulting with all of the county health departments, the agency, and all the local chapters of the American Red Cross or other lead sheltering agency in the areas of operation for that particular hospice~~. The Department of Health shall complete its review to ensure that the plan is in accordance with the criteria set in the Department of Elderly Affairs rule within 90 days after receipt of the plan and shall either approve the plan or advise the hospice of necessary revisions. The Department of Health shall make every effort to avoid imposing on the hospice differing requirements based on differences between counties.

Section 10. Subsection (13) of section 400.925, Florida Statutes, is amended to read:

400.925 Definitions.--As used in this part, the term:

(13) Life-supporting or life-sustaining equipment means a device that is essential to or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life. Life-supporting or life-sustaining equipment includes apnea monitors, enteral feeding pumps, infusion pumps, portable home dialysis equipment, and ventilator equipment and supplies for all related equipment, including oxygen equipment and related respiratory equipment.

Section 11. Section 400.934, Florida Statutes, is created to read:

400.934 Minimum standards.--As a requirement of licensure, home medical equipment providers shall:

(20) Prepare and maintain a comprehensive emergency management plan that meets minimum criteria established by the agency in rule pursuant to 400.935, F.S. The plan shall be updated annually and shall provide for continuing home medical equipment services for life-supporting or life-sustaining equipment, as defined in 400.925, F.S., during an emergency that interrupts home medical equipment services in the patient's home. The plan shall include how the home medical equipment provider will continue to provide equipment to perform the same type and quantity of services to their patients who evacuate to special needs shelters as staff were providing to those patients prior to evacuation. The plan shall describe how the home medical provider establishes and maintains an effective response to emergencies and disasters, including: notifying staff when emergency response measures are initiated; providing for communication between staff members, county health departments, and local emergency management agencies, including a backup system; identifying resources necessary to continue essential care or services or referrals to other organizations subject to written agreement; and prioritizing and contacting consumers who need continued medical equipment services and supplies.

(a) The plan is subject to review and approval by the county health department. During its review, the county health department shall contact state and local health and medical stakeholders, when necessary. The county health department shall complete its review to ensure that the plan is in accordance with the criteria set in the Agency for Health Care Administration rule within 90 days after receipt of the plan.

If a home medical equipment provider fails to submit a plan or fails to submit requested information or revisions to the county health department within 30 days after written

notification from the county health department, the county health department shall notify the Agency for Health Care Administration. The agency shall notify the home medical equipment provider that such failure constitutes a deficiency, subject to a fine of $5,000 per occurrence. If the plan is not submitted, information is not provided, or revisions are not made as requested, the agency may impose the fine.

(b) For any home medical equipment provider that operates in more than one county, the Department of Health shall review the plan. The Department of Health shall complete its review within 90 days after receipt of the plan and shall either approve the plan or advise the home medical provider of necessary revisions. The Department of Health shall make every effort to avoid imposing differing requirements based on differences between counties on the home medical equipment provider.

(1) Each home medical equipment provider shall maintain a current prioritized list of patients who needs continued services during an emergency. The list shall indicate how services shall be continued in the event of an emergency or disaster for each consumer and if the consumer is to be transported to a special needs shelter, and shall indicate if the consumer has life-supporting or life-sustaining equipment, including the specific type of equipment and related supplies. The list shall be furnished to county health departments and to local emergency management agencies, upon request.

(2) Home medical equipment providers may establish links to local emergency operations centers to determine a mechanism to approach areas within the disaster in order for the provider to reach its patients.

Section 12. Section 400.935, Florida Statutes, is amended to read:

400.935 Rules establishing minimum standards.--The agency shall adopt, publish, and enforce rules to implement this part, which must provide reasonable and fair minimum standards relating to:

(10) Home medical equipment requiring home medical equipment services.

(11) Preparation of a comprehensive emergency management plan pursuant to s. 400.934.

(a) The Agency for Health Care Administration shall adopt rules establishing minimum criteria for the plan, including maintaining patient equipment and supply lists that can accompany patients who are transported from their homes, in consultation with the Department of Health and the Department of Community Affairs.

Section 13. Section 408.831, Florida Statutes, is amended to read:

408.831 Denial, suspension, or revocation of a license, registration, certificate, or application.--

(1) In addition to any other remedies provided by law, the agency may deny each application or suspend or revoke each license, registration, or certificate of entities regulated or licensed by it:

(a) If the applicant, licensee, registrant, or certificateholder, or, in the case of a corporation, partnership, or other business entity, if any officer, director, agent, or managing employee of that business entity or any affiliated person, partner, or shareholder having an ownership interest equal to 5 percent or greater in that business entity, has failed to pay all outstanding fines, liens, or overpayments

assessed by final order of the agency or final order of the Centers for Medicare and Medicaid Services, not subject to further appeal, unless a repayment plan is approved by the agency; or

(b) For failure to comply with any repayment plan.

(2) In reviewing any application requesting a change of ownership or change of the licensee, registrant, or certificateholder, the transferor shall, prior to agency approval of the change, repay or make arrangements to repay any amounts owed to the agency. Should the transferor fail to repay or make arrangements to repay the amounts owed to the agency, the issuance of a license, registration, or certificate to the transferee shall be delayed until repayment or until arrangements for repayment are made.

(3) Entities subject to this section may exceed their licensed capacity to act as a receiving facility in accordance with an emergency operations plan for clients of evacuating providers from a geographic area where an evacuation order has been issued by a local authority having jurisdiction. While in an overcapacity status, each provider must furnish or arrange for appropriate care and services to all clients. In addition, the agency shall approve requests for overcapacity beyond 15 days, which approvals may be based upon satisfactory justification and need as provided by the receiving and sending facility.

(4) An inactive license may be issued to a licensee subject to this section when the provider is located in a geographic area where a state of emergency was declared by the Governor of Florida if the provider:

(a) Suffered damage to the provider's operation during that state of emergency.

(b) Is currently licensed.

(c) Does not have a provisional license.

(d) Will be temporarily unable to provide services but is reasonably expected to resume services within 12 months.

An inactive license may be issued for a period not to exceed 12 months but may be renewed by the agency for up to 6 additional months upon demonstration to the agency of progress toward reopening. A request by a licensee for an inactive license or to extend the previously approved inactive period must be submitted in writing to the agency, accompanied by written justification for the inactive license which states the beginning and ending dates of inactivity and includes a plan for the transfer of any clients to other providers and appropriate licensure fees. Upon agency approval, the licensee shall notify clients of any necessary discharge or transfer as required by authorizing statutes or applicable rules. The beginning of the inactive licensure period shall be the date the provider ceases operations. The end of the inactive period shall become the licensee expiration date and all licensure fees must be current, paid in full, and may be prorated. Reactivation of an inactive license requires the prior approval by the agency of a renewal application, including payment of licensure fees and agency inspections indicating compliance with all requirements of this part and applicable rules and statutes.

(5) ~~(3)~~ This section provides standards of enforcement applicable to all entities licensed or regulated by the Agency for Health Care Administration. This section controls over any conflicting provisions of chapters 39, 381, 383, 390, 391, 393, 394, 395, 400, 408, 468, 483, and 641 or rules adopted pursuant to those chapters.

Section 14. This act shall take effect July 1, 2006.

========== T I T L E A M E N D M E N T ==========

Remove the entire title and insert:

A bill to be entitled

An act relating to emergency management; amending s. 252.355, F.S.; specifying additional agencies that are required to provide registration information to persons with disabilities or special needs who receive services from such agencies for purposes of inclusion within the registry of persons with special needs maintained by local emergency management agencies; providing that the Department of Community Affairs shall be the designated lead agency responsible for community education and outreach to the general public, including persons with special needs, regarding registration as a person with special needs, special needs shelters, and general information regarding shelter stays; requiring the department to disseminate educational and outreach information through local emergency management offices; requiring the department to coordinate community education and outreach related to special needs shelters with specified agencies and entities; providing that special needs shelters must allow persons with disabilities to bring service animals into all areas of a special needs shelter; providing that specified confidential and exempt information relating to registration of persons with special needs be provided to the Department of Health; creating s. 252.3568, F.S.; requiring the Division of Emergency Management to address evacuation of persons with pets in the shelter component of the state comprehensive emergency management plan; creating s. 252.357, F.S., requiring the Florida Comprehensive Emergency Management Plan to permit the Agency for Health Care

Administration to make initial contact with each nursing home in a disaster area; requiring the agency to annually publish an emergency telephone number that may be used by nursing homes to contact the agency; amending s. 252.385, F.S.; revising provisions relating to public shelter space; requiring the Division of Emergency Management of the Department of Community Affairs to biennially prepare and submit a statewide emergency shelter plan to the Governor and the Cabinet for approval; providing plan requirements; requiring the Department of Health to assist the division in determining the estimated need for special needs shelter space and the adequacy of the facility to meet the needs of special needs persons; requiring the division to include information on the availability of pet friendly shelters in the statewide emergency shelter plan; revising those facilities which are excluded as being suitable for use as public hurricane evacuation shelters; requiring local emergency management agencies to inspect a designated facility to determine its readiness prior to activating such facility for a specific hurricane or disaster; amending s. 381.0303, F.S.; providing for the operation, maintenance, and closure of special needs shelters; providing that the local Children's Medical Services offices shall assume lead responsibility for specified coordination with respect to the development of a plan for the staffing and medical management of pediatric special needs shelters; requiring such plans to conform to the local comprehensive emergency management plan; requiring county governments to assist in the process of coordinating the recruitment of health care practitioners to staff local special needs shelters; the Department of Health with nonmedical staffing and the operation of special needs shelters; requiring local health departments and emergency management agencies to

coordinate such efforts to ensure appropriate staffing in special needs shelters;

providing that the appropriate county health department, Children's Medical Services office, and local emergency management agency shall jointly determine the responsibility for medical supervision in a special needs shelter; providing notification requirements; requiring local emergency management agencies to be responsible for the designation, operation, and infrastructure of special needs shelters during times of emergency or disaster and the closure of the facilities following an emergency or disaster; requiring the emergency management agency and the local health department to coordinate efforts to ensure appropriate designation, operation, and infrastructure in special needs shelters; providing that state employees with a preestablished role in disaster response may be called upon to serve in times of disaster in specified capacities; requiring the Secretary of Elderly Affairs to convene a multiagency emergency special needs shelter discharge planning team or teams to assist local areas that are severely impacted by a natural or manmade disaster that required the use of special needs shelters; providing duties and responsibilities of multiagency discharge planning teams; authorizing local emergency management agencies to request the assistance of a multiagency discharge planning team; providing for the inclusion of specified state agency representatives on each multiagency discharge planning team; authorizing hospitals, nursing homes, assisted living facilities, and hospices that are used to shelter special needs persons during or after an evacuation to submit invoices for reimbursement to the Department of Health; requiring the department to specify by rule expenses that are reimbursable and the rate of reimbursement for services;

prescribing means of and procedures for reimbursement; providing eligibility for reimbursement of health care facilities to whom special needs shelter clients have been discharged by a multiagency special needs shelter discharge planning team upon closure of a special needs shelter; providing requirements with respect to such reimbursement; prescribing means of and procedures for reimbursement; disallowing specified reimbursements; revising the role of the special needs shelter interagency committee with respect to the planning and operation of special needs shelters; providing required functions of the committee; revising the composition of the special needs shelter interagency committee; requiring the department to adopt rules with respect to special needs shelters; providing requirements with respect to emergency management plans submitted by a home health agency, nurse registry, hospice, or home medical equipment provider to a county health department for review; amending s. 400.492, F.S.; requiring the comprehensive emergency management plan to include the means by which a home health agency will continue to provide staff to provide services to their patients who evacuate to special needs shelters; authorizing home health agencies to establish links to local emergency operations centers to determine a mechanism to approach areas within a disaster area in order for the agency to reach its clients; providing that the presentation of home care or hospice clients to the special needs shelter without the home health agency or hospice making a good faith effort to provide services in the shelter setting constitutes abandonment of the client and constitutes a Class II deficiency, subject to sanctions under s. 400.484, F.S.; amending s. 400.497, F.S., revising requirements of a county health department with respect to review of a comprehensive emergency management plan;

providing requirements of a county health department in the event that a home health agency fails to submit a plan or fails to submit requested information or revisions to the department within a specified period after written notification; providing notification requirements; providing for imposition of a fine; amending s. 400.506, F.S., relating to licensure of nurse registries; revising requirements of a nurse registry with respect to the preparation of a comprehensive emergency management plan; providing requirements of a county health department in the event that a nurse registry fails to submit a plan or fails to submit requested information or revisions to the department within a specified period after written notification; providing notification requirements; providing for imposition of a fine; providing requirements of the Department of Health with respect to review of the plan; amending s. 400.610, F.S.; relating to administration and management of a hospice; revising requirements of a hospice with respect to the preparation of a comprehensive emergency management plan that provides for continuing hospice services in the event of an emergency; providing that the presentation of hospice clients to a special needs shelter without the hospice making a good faith effort to provide services in the shelter setting constitutes abandonment of the client; providing requirements of the Department of Health with respect to review of the plan; amending s. 400.925, F.S.; defining "life-supporting or life-sustaining equipment"; amending s. 400.934, F.S.; requiring home medical equipment providers to prepare and maintain a comprehensive emergency management plan that meets minimum criteria established by the Agency for Health Care Administration as a requirement of licensure; providing procedures and requirements with respect thereto;

amending s. 400.935, F.S.; requiring home medical equipment services providers to prepare a comprehensive emergency management plan; requiring the Agency for Health Care Administration to adopt rules establishing minimum criteria for the plan; amending s. 408.831, F.S.; providing that entities regulated or licensed by the Agency for Health Care Administration may exceed their licensed capacity to act as a receiving facility under specified circumstances; providing requirements while such entities are in an overcapacity status; providing for issuance of an inactive license to such licensees under specified conditions; providing requirements and procedures with respect to the issuance and reactivation of an inactive license; providing fees; creating s. 252.357, F.S., requiring the Florida Comprehensive Emergency Management Plan to permit the Agency for Health Care Administration to initially contact nursing homes in disaster areas for specified monitoring purposes; requiring the agency to publish an emergency telephone number for use by nursing homes; providing an effective date.

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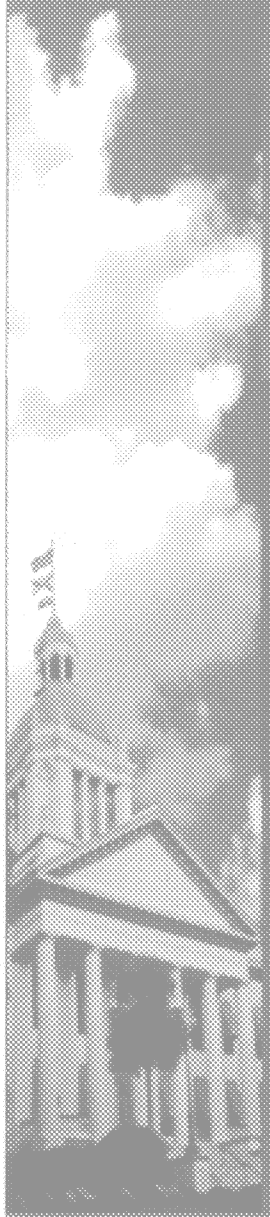


Inflated Pricing & Confidential Information Prevent Medicaid from Ensuring Lowest Prescription Drug Prices

A Presentation to the House Health Care General Committee

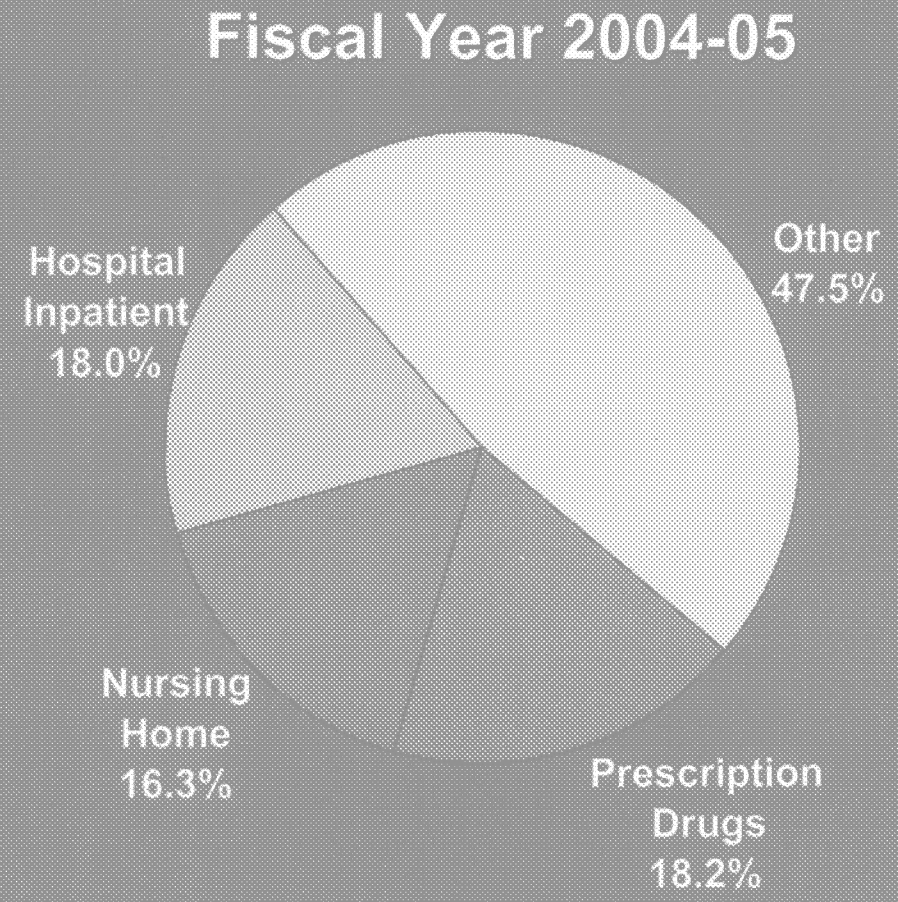
February 22, 2006

Jennifer Johnson, Senior Legislative Analyst

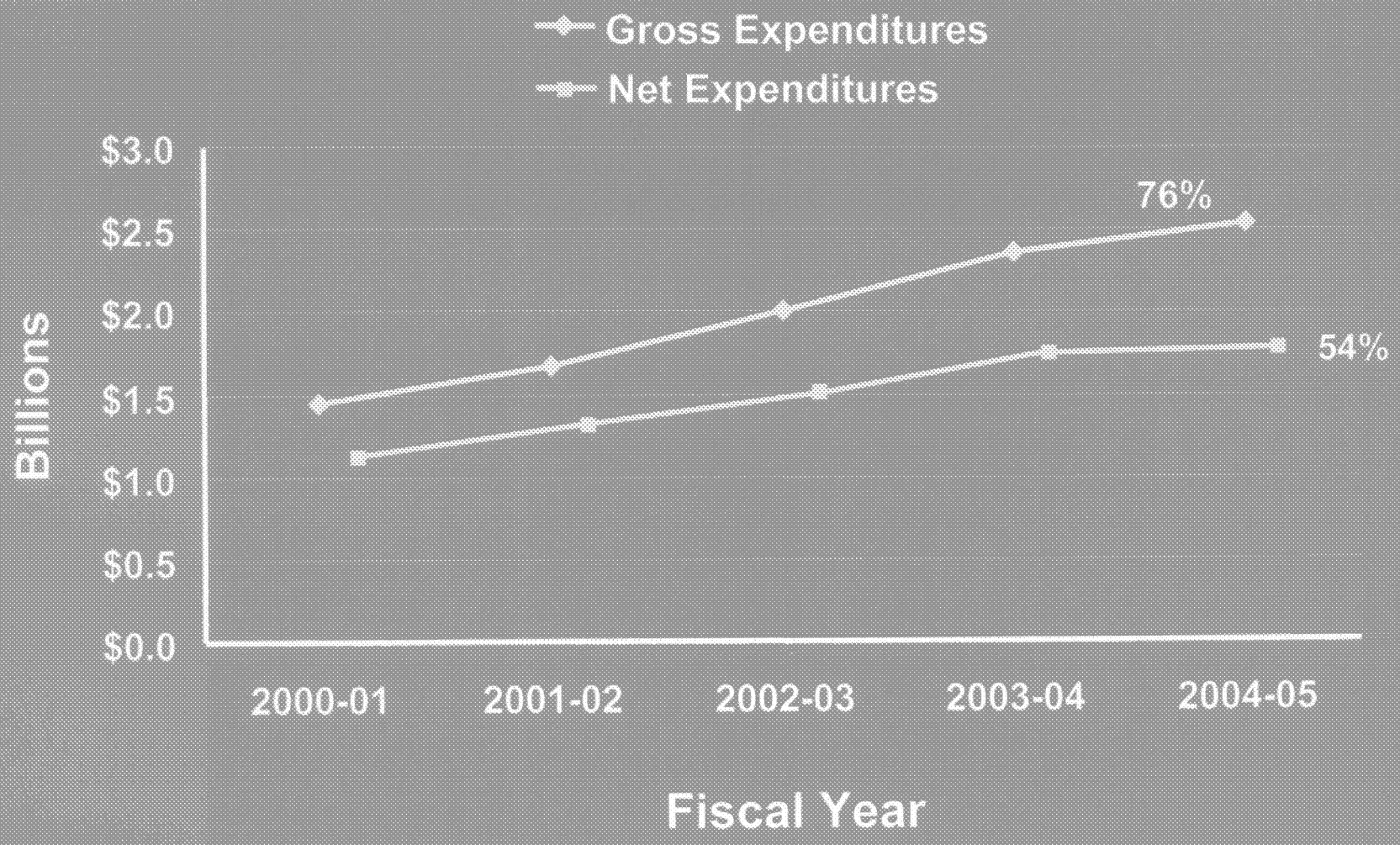
Presentation Overview

- Medicaid drug expenditures
- Medicaid drug pricing in Florida
- Flaws in Medicaid pricing
- Recommendations

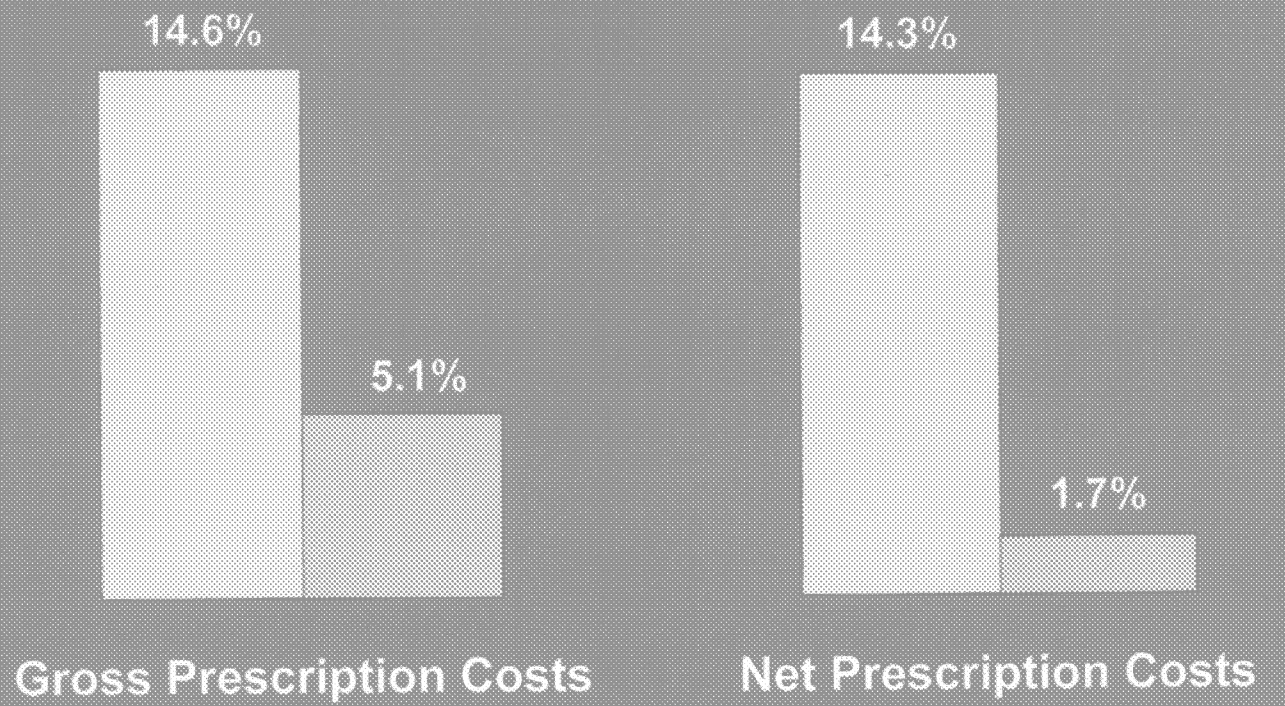
Prescription Drugs Accounted for 18.2% of Medicaid Spending



Medicaid Drug Expenditures



Average Prescription Cost Increased at a Slower Rate



Florida Medicaid Drug Prices

1. Pharmacy reimbursements
2. Federal and state supplemental rebates

Pharmacy Reimbursements

Federal guidelines direct states to reimburse pharmacies the lower of the:

- *Estimated acquisition cost* plus dispensing fee, or
- Usual and customary price

Estimated Acquisition Cost

AHCA determines *estimated acquisition costs* by calculating and selecting the lowest of the following:

- Average Wholesale Price (AWP) - 15.4%
- Wholesale Acquisition Cost (WAC) + 5.75%
- The Federal Upper Limit (FUL)
- The State Maximum Allowable Cost (SMAC)

Fundamental Flaws (cont.)

- Average Manufacturer Price is a better benchmark for estimating acquisition costs
- However, it is confidential and most states do not have access to it

Recommendations

- Require manufacturers to submit AMP and 'Net Wholesaler Price' and direct AHCA to use information to reimburse pharmacies
  - Federal legislation passed by Congress will allow states access to AMP for Medicaid pricing
  - Texas requires manufacturers to submit AMP and 'net wholesaler prices'

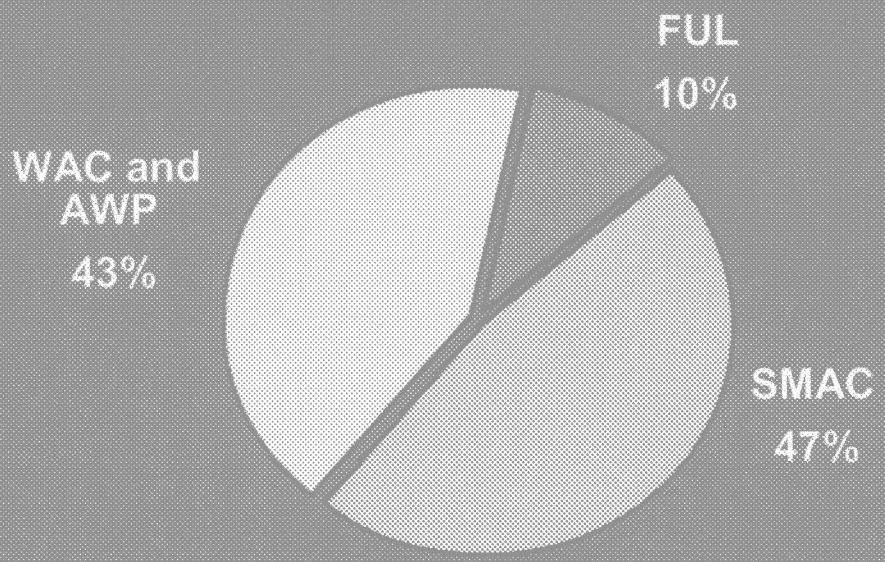
Recommendations

Modify formulas for estimating pharmacy acquisition costs

Drug Type	Revised Discount Price	Approximate Savings Against Fiscal Year 2004-05 Expenditures
Brand Name Drug	AWP-17%	$ 4.6 million
Generics[1]	AWP-40%	20.0 million
Total		$24.6 million

Recommendations

Expand state maximum allowable costs for generic drugs and update more frequently



In the fourth quarter of FY 2004-05, the SMAC price was the lowest price for only 47% of drugs with a SMAC price

Recommendations

- Negotiate supplemental rebates for generic drugs
  - Adjust dispensing fee to encourage pharmacies to dispense generic drugs that receive rebates
- Evaluate joining a purchasing pool
  - Medicare Part D may affect ability to negotiate supplemental rebates

For Additional Information

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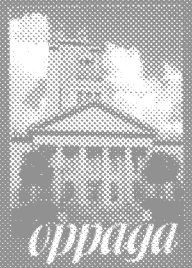
Report available online at:
www.oppaga.state.fl.us/reports/govt/r06-07s.html

Thank you



Office of Program Policy Analysis & Government Accountability

OPPAGA supports the Florida Legislature by providing evaluative research and objective analyses to promote government accountability and the efficient and effective use of public resources.

The Epidemiologic Study on Crohn's Disease and Ulcerative Colitis

HB 869 ER (Section 2)

Bureau of Epidemiology

Florida Department of Health

Background

- Crohn's disease and ulcerative colitis (IBD) are serious chronic disorders of the gastrointestinal tract
- Approximately 1.4 million Americans are afflicted
- No previous research conducted on IBD in Florida
- "Crohn's and Colitis Disease Research Act" (HB869 ER (Section 2)) requires the Florida Department of Health to conduct an epidemiologic study on IBD

Partners

- UF
- AHCA
- CCFA*
- Blue Cross Blue Shield
- Medical providers

* Crohn's and Colitis Foundation of America

Purpose

- Determine:
  - Prevalence of IBD in Florida
  - Demographic characteristics of IBD patients
  - Role of environmental and genetic risk factors

Implementation of the Study

- Literature review
- Consultations from experts
- Advisory Committee
- Epidemiologic study
- Information dissemination

Literature Review

- Rate of IBD
  - Crohn's disease: 162 per 100,000 to 199 per 100,000
  - Ulcerative colitis: 170 per 100,000 to 246 per 100,000

Literature Review

- Characteristics of IBD patient:
  - Females > 50%
  - Mean age at diagnosis: 33.4 - 45 years
  - Non-Hispanic Whites had a higher rate
- Factors Associated with IBD
  - Family history
  - Smoking

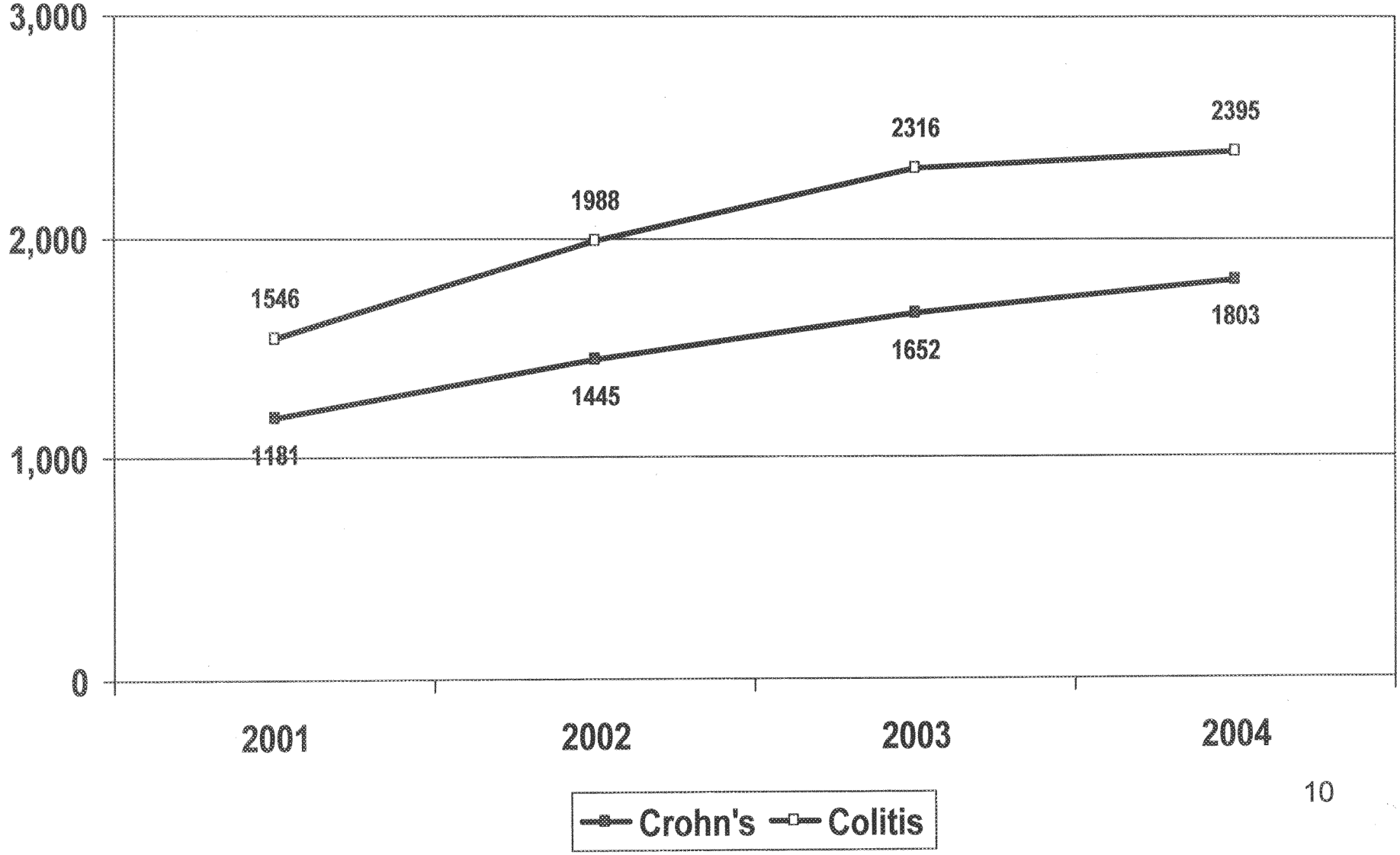
Consultations from Experts

- **CDC**: Sean Cucchi and Siobhán O'Connor
- **CCFA:** Suzanne Rosenthal, Marjorie Merrick and Florida representatives
- **University of Miami:** Amy Trachter
- **Medical College of Wisconsin:** Subra Kugathasan
- **Shafran Gastroenterology Center**: Ira Shafran
- **Kaiser Permanente:** Lisa Herrinton
- **Crohn's and Colitis support group**: David Wolff

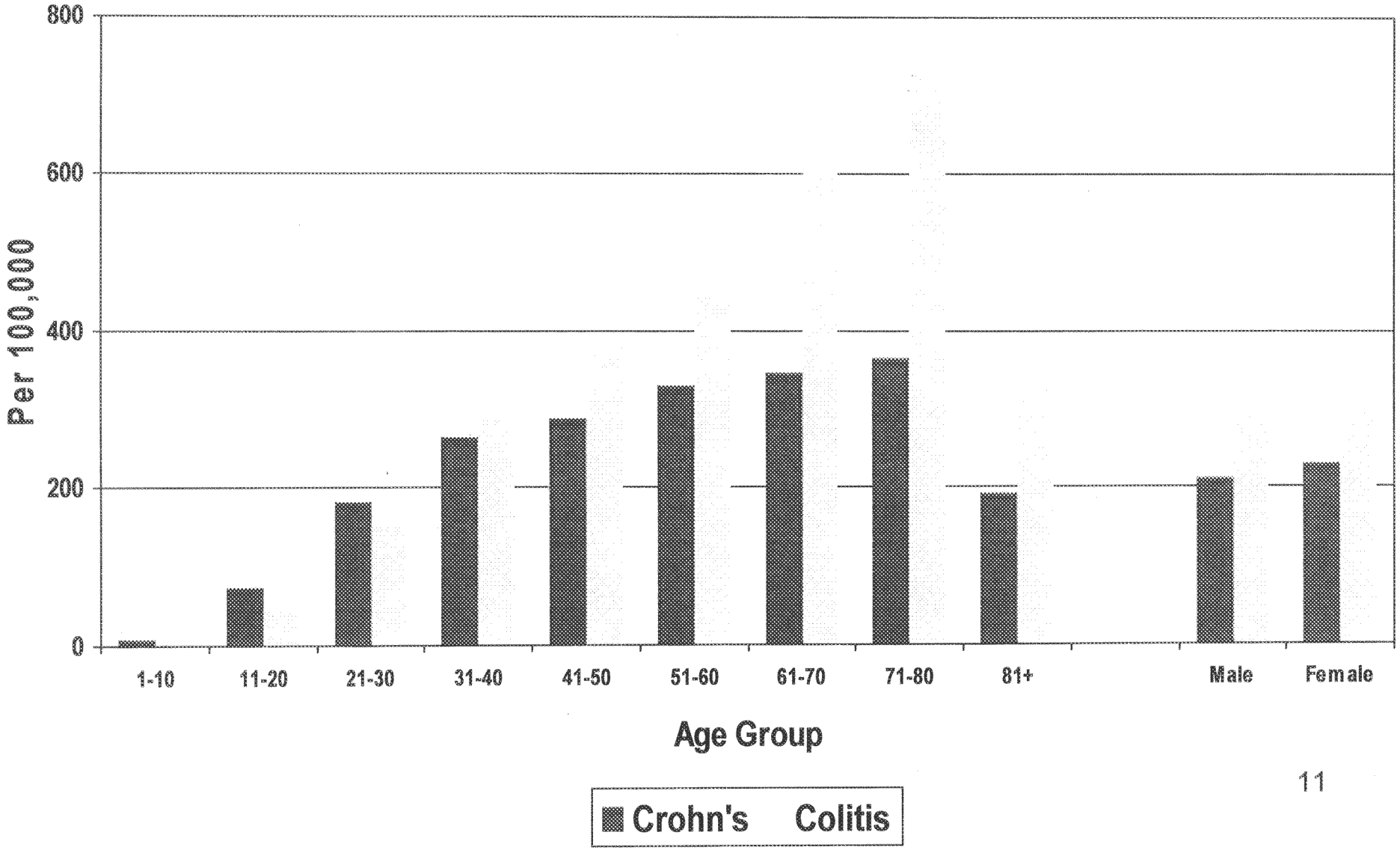
Advisory Committee

- **DOH**: Lisa Fisher, Regan Glover, Youjie Huang, Curt Miller, Heather Murphy, Mike Paredes, and Dian Sharma
- **UF**: Paul Duncan, Chris Jolley, Robert Frank, and John Valentine
- **AHCA**: Gloria Barker, Mel Chang, Susan Chen, Beth Eastman, Adrienne Henderson, Lisa Rawlins, and Cliff Schmidt
- **BCBS**: John Bookstaver, Randy Kammer, John Montgomery, David Pizzi, and John Williams
- **Florida House Representative**: Eleanor Sobel
- **Florida Senate**: Gwen Margolis
- **Physician and Psychologist** : Laurence Adams, Amy Trachter
- **Tidewater Consulting, Inc.**: Frank Mayernick
- **CCFA**: Kiren Annigeri, Marlene Bluestein, Toby Gordon, Marjorie Merrick, Suzanne Rosenthal, Allison Silver, Ellen Shapiro, Kelly Stouten, and Dave Wolff
- **CDC**: Sean Cucchi and Siobhan O'Connor
- **Kaiser Permanente**: Lisa Herrinton

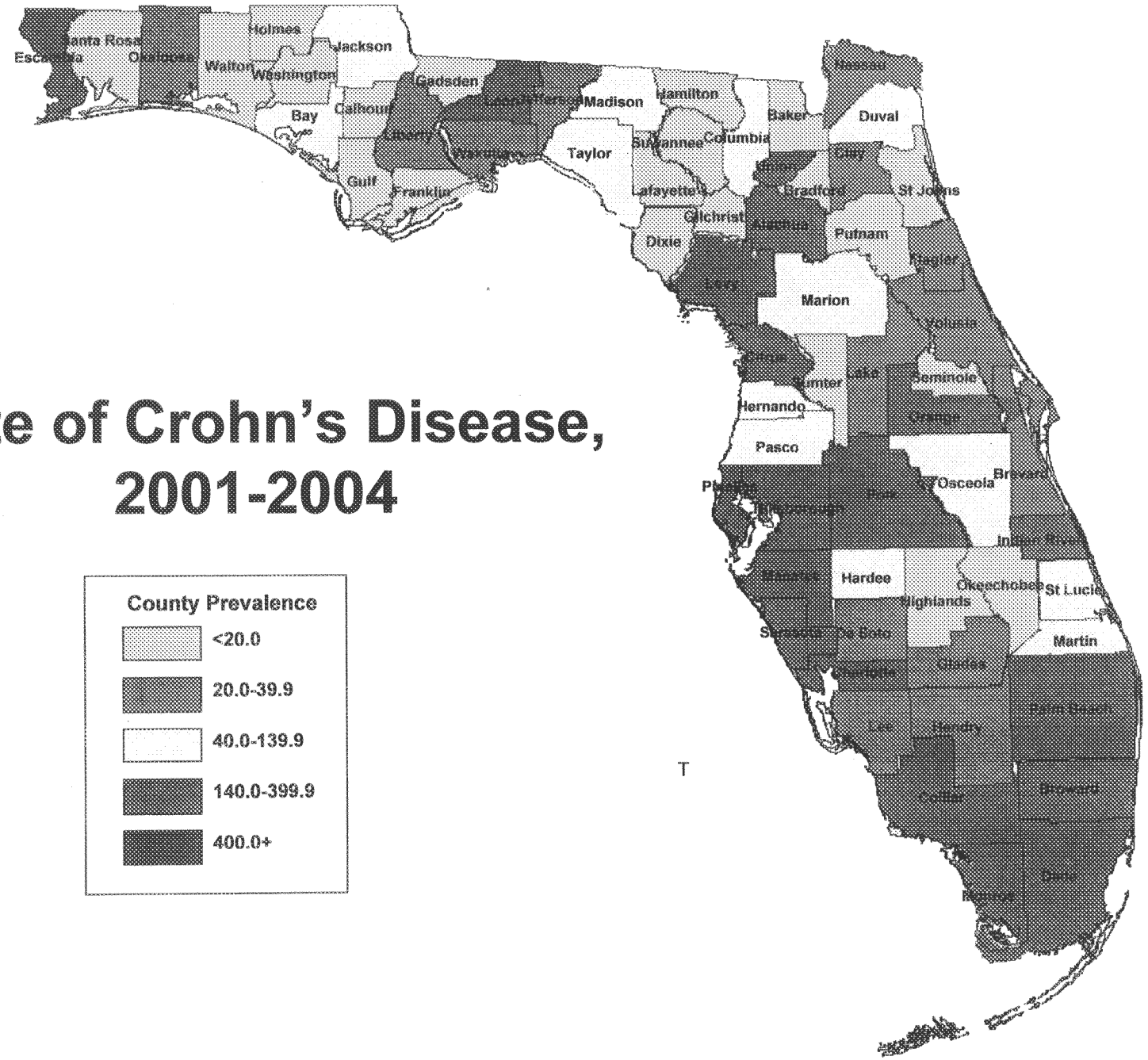
Number of New IBD Patients among BCBS Members, 2001-2004



Rate of IBD among BCBS Members 2001-2004



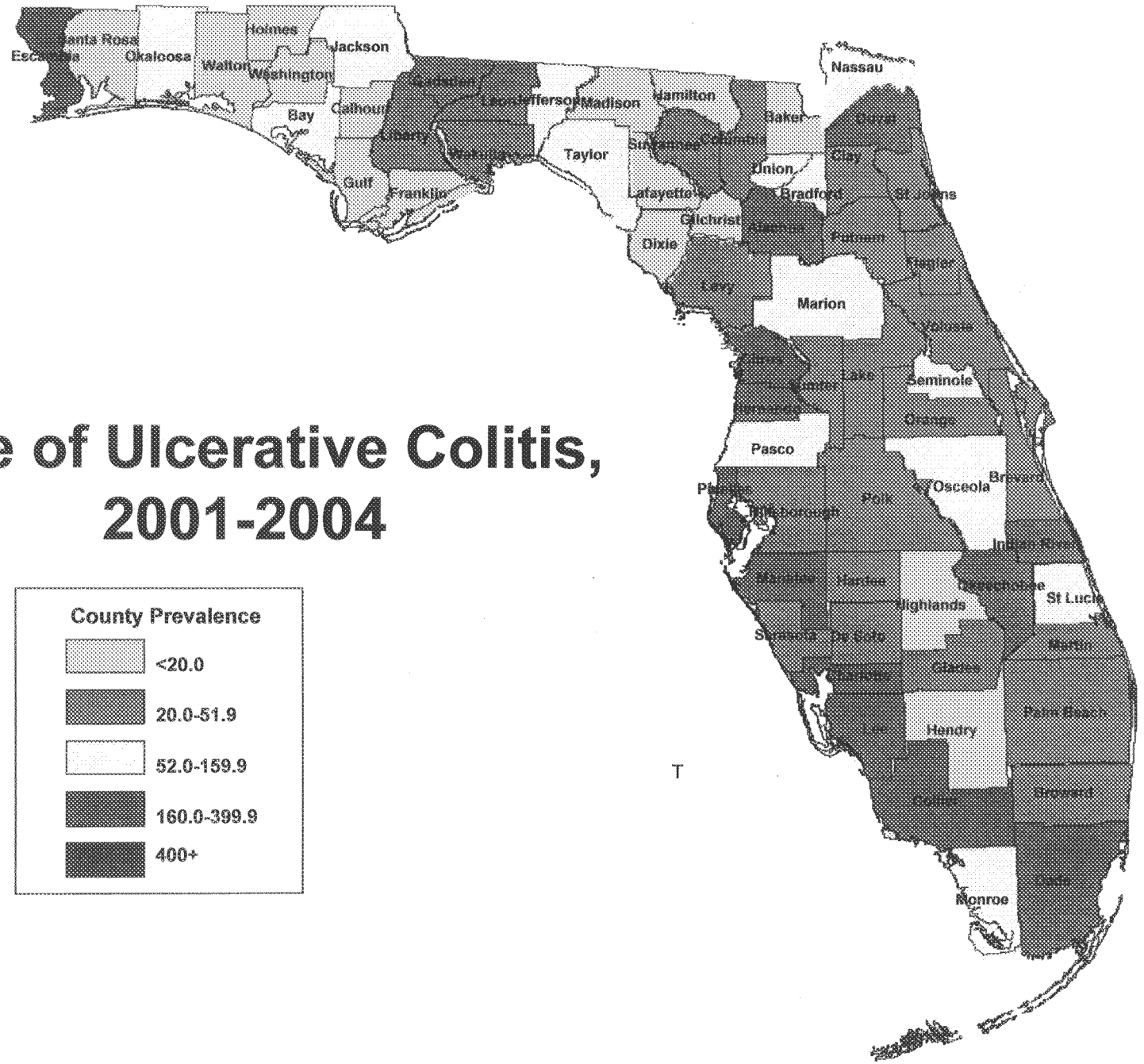
Rate of Crohn's Disease, 2001-2004



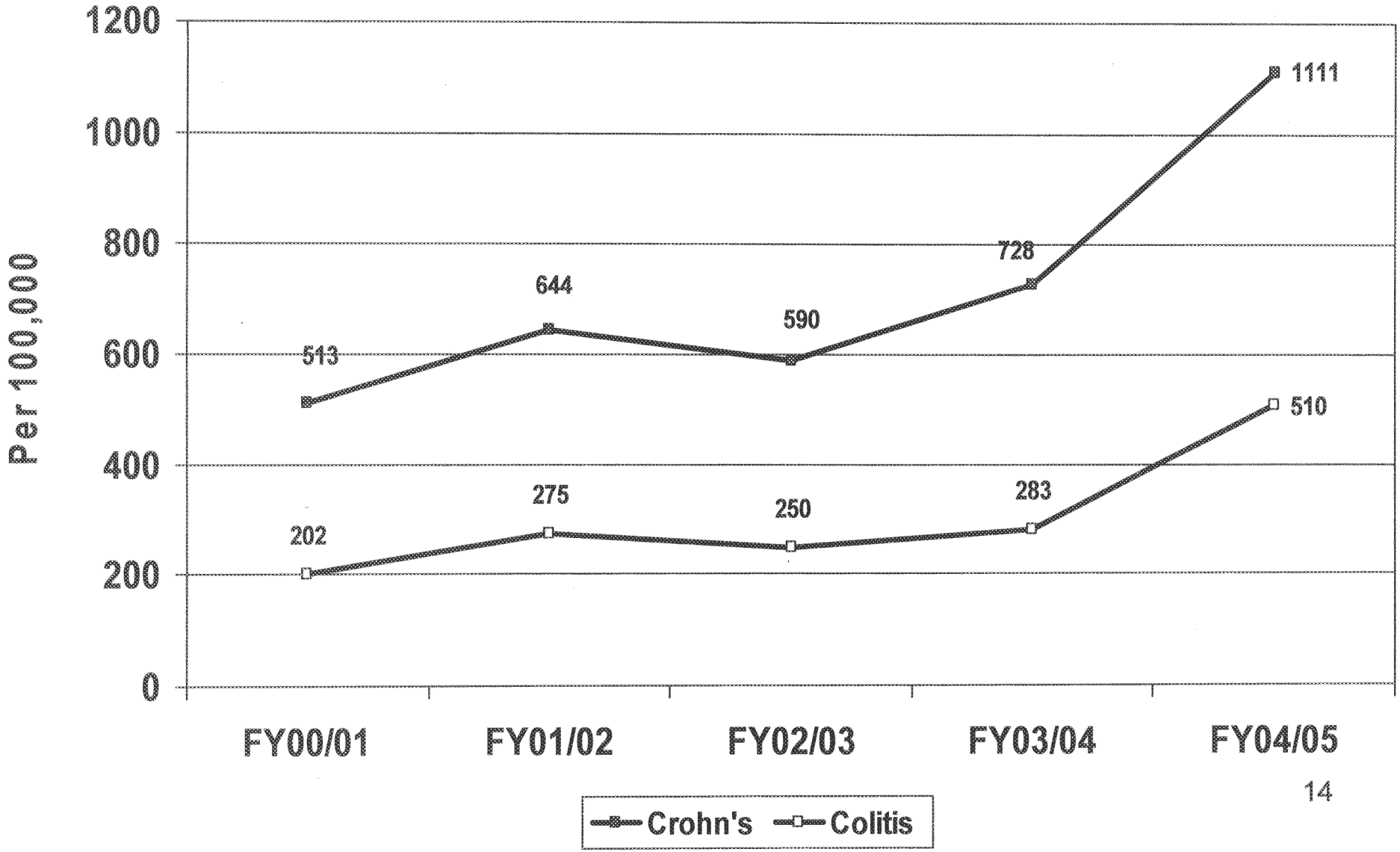
County Prevalence

- <20.0
- 20.0-39.9
- 40.0-139.9
- 140.0-399.9
- 400.0+

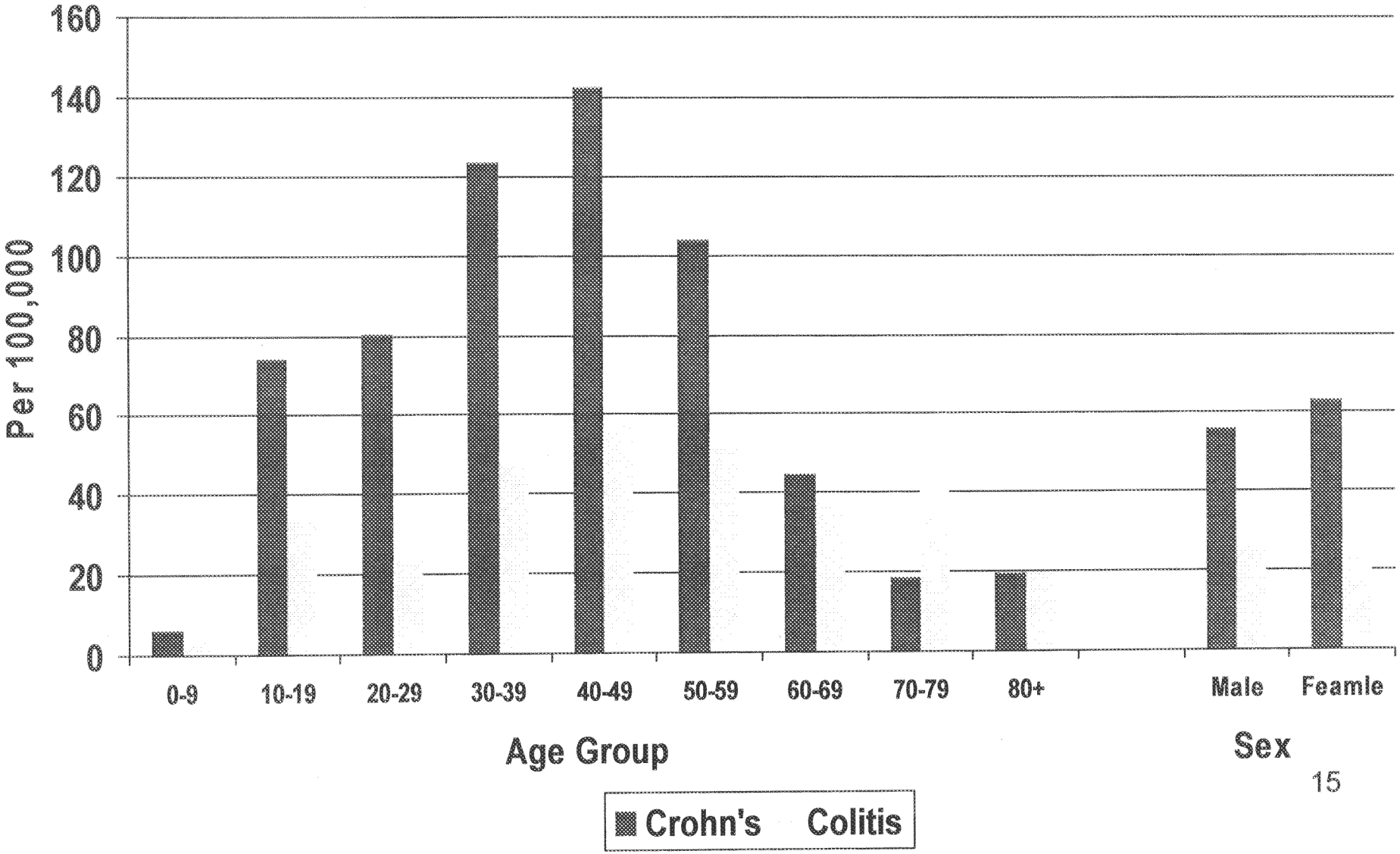
Rate of Ulcerative Colitis, 2001-2004



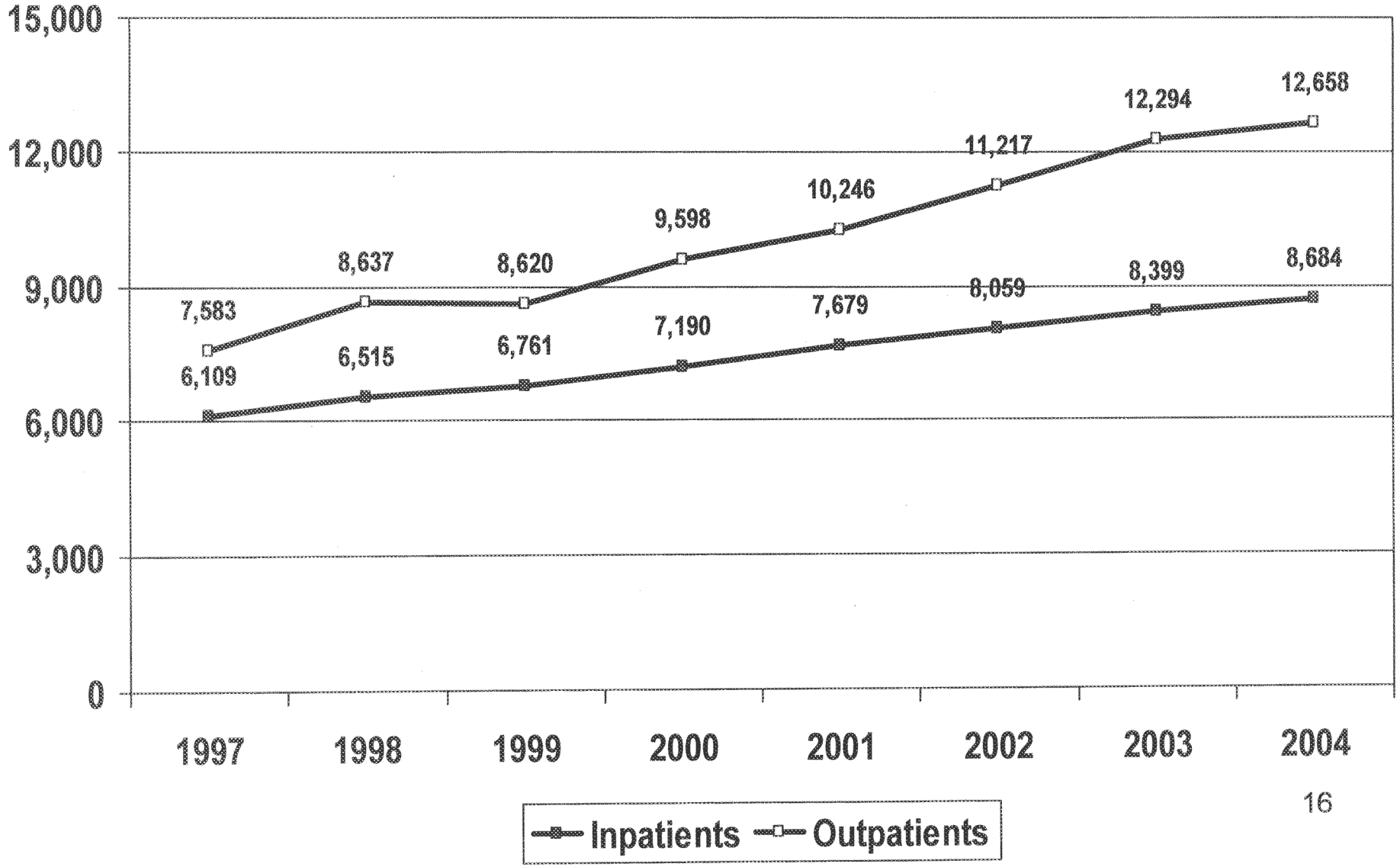
Number of New IBD Cases among Medicaid Recipients, FY00/01 – FY04/05



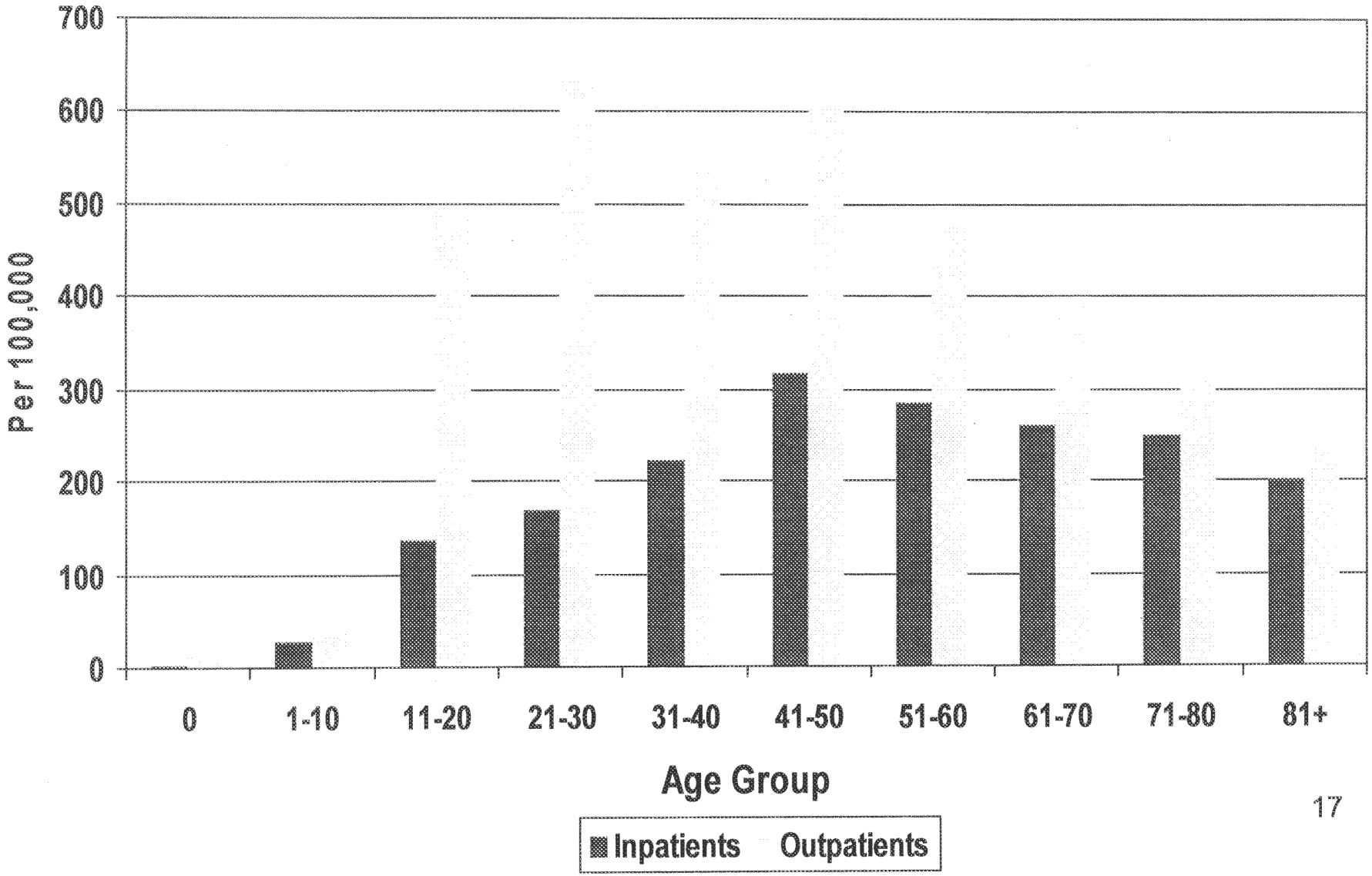
Rate of IBD among Medicaid Recipients, FY00/01- FY04/05



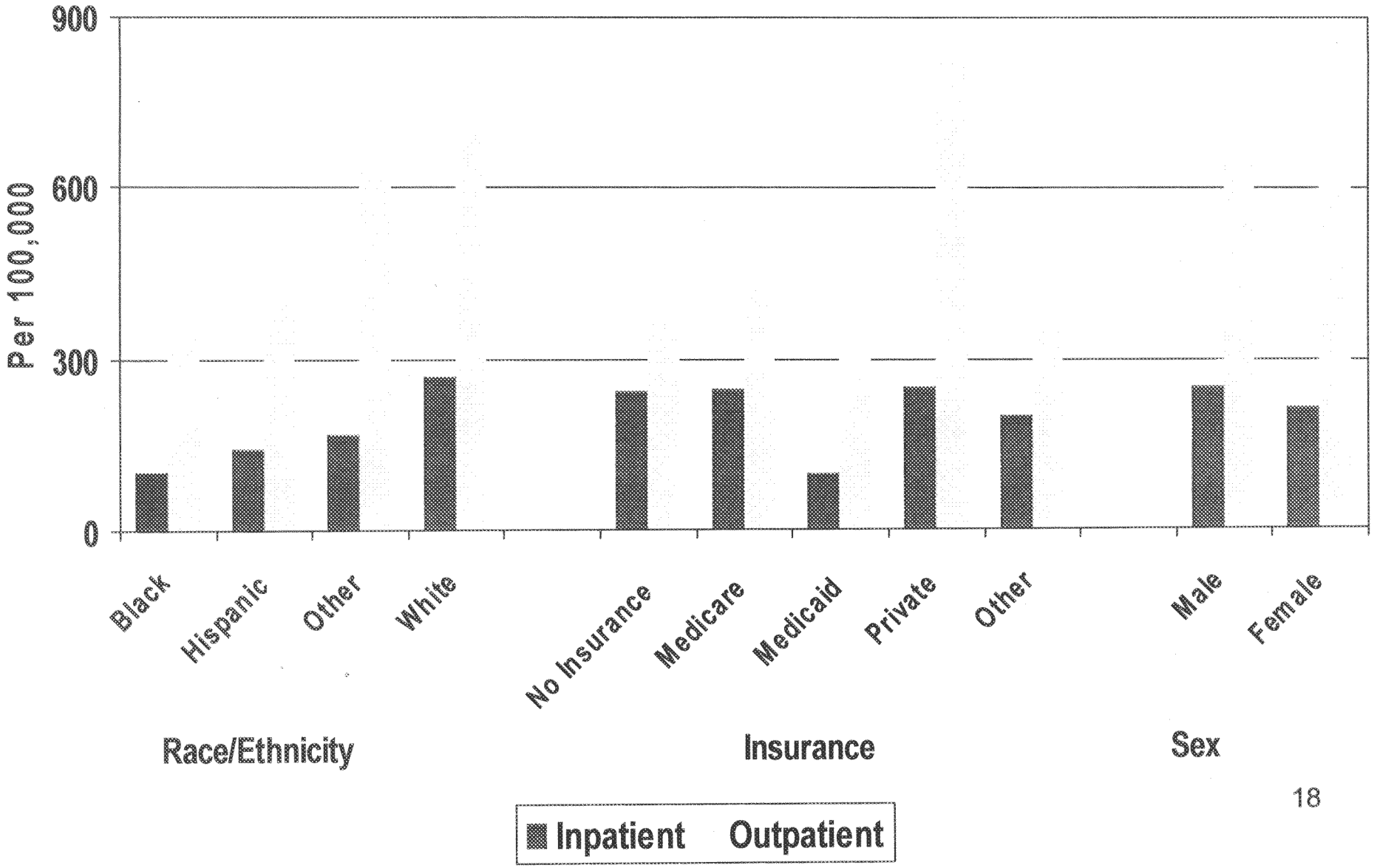
Number of IBD Inpatients and Outpatients, 1997-2004



Rate of IBD Inpatients and Outpatients, 1997-2004



Rate of IBD Inpatients and Outpatients 1997-2004



Surveys: BRFSS

- 3.8% of 1,659 survey respondents reported IBD in their household.
- 4.8% of 63 households had more than one patient
- 18.2% patients were hospitalized in the past year.

Surveys: Physicians and Patients

- 113 physicians
  - 14% diagnosed in the past 12 months;
  - 40% between age 20 and 45 years
  - 93% white and 5% African Americans
  - 22% had a family history
- 27 patients
  - Average time with IBD: 11.1 years
  - 96% whites, 33% Jewish decent
  - 18% with a family history
  - 18% rated their health as poor

Conclusions

- Estimated rate: 529 per 100,000
  - Crohn's disease: 222 per 100,000 persons
  - Ulcerative colitis: 307 per 100,000 persons
- Estimated number of patients: 84,500
  - 35,500 with Crohn's disease
  - 49,000 with ulcerative colitis

Conclusions

- The rate is higher among:
  - Young and middle age adults
  - Non-Hispanic Whites
  - Residents in Sarasota and Palm Beach counties
- Family history suggests genetic factors associated with IBD
- No environmental factors were identified or confirmed in this study

Final Report of The Epidemiologic Study on Crohn's Disease and Ulcerative Colitis

HB 869 ER (Section 2)

Prepared by

Bureau of Epidemiology
Florida Department of Health

February 1, 2006

Jeb Bush
Governor

M. Rony François, M.D., M.S.P.H., Ph.D.
Secretary, Department of Health

EXECUTIVE SUMMARY

Crohn's disease and ulcerative colitis, collectively known as Inflammatory Bowel Disease (IBD), are serious chronic disorders of the gastrointestinal tract. On June 10, 2005, Governor Jeb Bush signed House Bill 869 entitled "Crohn's and Colitis Disease Research Act" that requires the Florida Department of Health (DOH) to conduct an epidemiologic study on IBD. The goal of this epidemiologic study is to determine: (1) the prevalence of Crohn's disease and ulcerative colitis in Florida; (2) the demographic characteristics of patients with Crohn's disease and ulcerative colitis; and (3) the role of environmental and genetic risk factors in the development of Crohn's disease and ulcerative colitis. The act became effective on July 1, 2005, and the final report is due on February 1, 2006.

An advisory committee was developed for the epidemiologic study. The committee members consisted of representatives and researchers at DOH, the University of Florida, Agency for Health Care Administration (AHCA), Blue Cross Blue Shield (BCBS), Crohn's and Colitis Foundation of America (CCFA), members of the House of Representatives and the Senate, physicians, other medical providers, and other interested groups. Monthly conference calls and an in-person conference were held for the committee members to guide the study.

The study was designed based on an extensive literature review of previous epidemiologic studies and recommendations from national experts. This study received support from the Secretary of the Department of Health, medical providers, and IBD patients throughout the state.

BCBS and AHCA provided large healthcare claim datasets, including BCBS data, Medicaid data, hospital discharge data, and ambulatory patient data. The DOH team conducted gastroenterology physician surveys, an IBD patient survey, and a statewide survey of general population through the Behavioral Risk Factor Surveillance System (BRFSS). The definition of IBD was based on a set of International Classification of Disease Version 9 (ICD-9) codes.

The study collected healthcare claim data with more than 42 million unduplicated records in up to 10 years, and surveyed more than 2,000 households, medical providers, and IBD patients statewide during the study period. The data were analyzed by patient's gender, race/ethnicity, age, residential county, household income, and type of health insurance. Statewide prevalence and number of IBD patients were estimated based on the data of this study and make-up of Florida population.

It is estimated that the prevalence of Crohn's disease is 222 per 100,000 persons and the prevalence of ulcerative colitis is 307 per 100,000 persons in Florida. It is also estimated that there are approximately 35,500 Crohn's disease patients and 49,000 ulcerative colitis patients in Florida. Approximately 11 percent of IBD patients are hospitalized and 12 percent of IBD patients are treated as ambulatory patients every year. The prevalence of IBD was higher among people ages 30 to 80 years old than among other age groups, higher among non-Hispanic Whites than among other race/ethnicity groups, and higher among females than among males. Medicaid recipients had the lowest prevalence rates in either inpatients or ambulatory patients. Sarasota and Palm Beach counties were the only two counties that had a high prevalence of Crohn's disease and ulcerative colitis in all hospital discharge data, ambulatory patient data, and BCBS data.

This study surveyed 27 IBD patients and found a high percent of non-Hispanic Whites, a high percent of patients with a family history, and a high percent of Jewish descents, which may

suggest an association between genetic factors and IBD. The survey examined several environmental factors based on literature reviews, including exposures to cigarette smoking, history of living near cattle and history of tonsillectomy or appendectomy. However, no causal relationship could be established between these risk factors and IBD due to the nature of the small survey of a convenient sample.

Future studies are recommended based on this study. These studies include: (1) a BRFSS survey with increased sample size to better estimate the population-based prevalence of IBD; (2) a case-control study to identify risk factors of IBD; and (3) an IBD patient voluntary registry through their providers. This registry will provide data for a longitudinal follow-up study of IBD patients on treatment, outcome, and quality of life.

Table of Contents

BACKGROUND

Crohn's disease and ulcerative colitis, collectively known as Inflammatory Bowel Disease (IBD), are serious chronic disorders of the gastrointestinal tract. Approximately 1.4 million Americans are afflicted with these illnesses, 30 percent of whom are diagnosed during childhood. IBD represents a major cause of morbidity from digestive illness, and ulcerative colitis patients are at high risk for developing colorectal cancer. Although IBD is rarely fatal, it is often devastating.

On November 30, 2004, President George W. Bush signed into law the first piece of legislation focused on Crohn's disease and ulcerative colitis, entitled the "Research Review Act." During the 108th Congress, the Crohn's and Colitis Foundation of America and its National IBD Advocacy Network advanced this legislation with three provisions for advancing research on IBD. Provisions were taken directly from legislation, entitled the "Inflammatory Bowel Disease Research Act." Within 12 months after the date of the enactment, the director of the Centers for Disease Control and Prevention was responsible for submitting a comprehensive plan to address the burden of inflammatory bowel disease, in both adult and pediatric populations, to the Senate Health, Education, Labor and Pensions Committee, the House Energy and Commerce Committee, and the House and Senate Appropriations Committee.

There is a perceived increase of IBD in Florida; however, no previous research has been conducted to reveal the prevalence of these illnesses among Florida residents. Therefore, the Florida State Legislature enacted the "Crohn's and Colitis Disease Research Act."

On June 10, 2005, Florida House Bill 869 was approved by Governor Jeb Bush. House Bill 869 is referred to as the "Crohn's and Colitis Disease Research Act." The act requires the Florida Department of Health (DOH) to conduct an epidemiologic study on inflammatory bowel disease in collaboration with the University of Florida College of Public Health and Health Professions, and requires the establishment of an IBD study group that must consist of representatives from the DOH, the Agency for Health Care Administration (AHCA), Crohn's and Colitis Foundation of America (CCFA), the House of Representatives, the Senate, medical providers, and other interested groups. The effective start date is July 1, 2005, and the final report is due to the Governor and the Florida Legislature by February 1, 2006.

PURPOSE OF THE STUDY

The purpose of this study is to work with the University of Florida and other agencies and organizations to conduct an epidemiologic investigation. The goal of this epidemiologic study is to determine the:

1. Prevalence of Crohn's disease and ulcerative colitis in Florida.
2. Demographic characteristics of patients with Crohn's disease and ulcerative colitis.
3. Role of environmental and genetic risk factors in the development of Crohn's disease and ulcerative colitis.

IMPLEMENTATION OF THE STUDY

Literature Review

As the first step of study design, DOH conducted an extensive literature review for studies on IBD. The project coordinator searched the Internet and journals to identify previous epidemiologic studies on both adult and childhood IBD. Through the literature review, DOH gathered information regarding potential and known IBD risk factors, epidemiologic and clinical characteristics of patients with IBD, and potential environmental exposures for IBD.

Drs. Robert Sandler and Edward Loftus (Sartor RB, Sandborn WJ, eds., Kirsner's *Inflammatory Bowel Diseases*, 6th ed., New York: Saunders, 2004) reviewed risk factors for IBD, including demographic characteristics of patients, diet, breast feeding and perinatal events, marital status, occupation and social class, oral contraceptives, cigarette smoking, non steroidal anti-inflammatory drugs, appendectomy, measles, and other miscellaneous factors. Sandler and Loftus conclude that there is undisputable evidence of heritable factors in the genesis of IBD, and environmental influence may attribute to 85-90 percent in ulcerative colitis and 50-55 percent in Crohn's disease. Smoking is highly associated with Crohn's disease, as is nonsmoking with ulcerative colitis. Truelove (Br Med J 1961:1:61) noted cow's milk might exacerbate symptoms of ulcerative colitis.

Dr. Edward Loftus (Gastroenterology, 2004:126:1504-17) states that previous studies have provided insight into the differences in incidence of IBD across age, time, and geographic region, suggesting that environmental factors can significantly modify the expression of these conditions. They suggest the strongest risk factors to be identified at this time are family history of IBD, cigarette smoking, and appendectomy. Research also suggests variation in the demographics of IBD patients:

- Gender: Females tend to have a predominance of Crohn's disease, whereas men tend to have a higher incidence of ulcerative colitis.
- Age: Both Crohn's disease and ulcerative colitis are most commonly diagnosed in late adolescence and early adulthood, however, the diagnosis may occur at any age.
- Race/Ethnicity: Although Whites have a higher incidence of IBD, the incidence among African Americans is approaching that of Whites. Asian Americans, Hispanic Americans, and aboriginal North Americans are less likely to develop IBD, especially Crohn's disease. Ethnic and racial differences may be more related to lifestyle and environmental influences than genetic differences.

Consultations from Experts

In addition to the literature search, DOH sought national and local experts to provide insights for developing Florida's IBD research plan. The project coordinator and the team consulted with many researchers nationwide for research methodology. The information received from these experts helped the Florida researchers refine the methodology of the IBD study. From August through December of 2005, DOH communicated with the following individuals and organizations for their suggestions and advice:

- Mr. Sean Cucchi and Dr. Siobhán O'Connor, Centers for Disease Control and Prevention (CDC), discussed the "Inflammatory Bowel Disease Research Act," which requires the CDC, in conjunction with CCFA, to conduct a national IBD epidemiology study. DOH requested information regarding CDC's research approach and methodology for data collection at the national level.

- Ms. Suzanne Rosenthal, CCFA Co-Founder, and Chairman of the Board Emeritus, and Marjorie Merrick, CCFA Vice President of Research and Scientific Programs provided contact information for national IBD experts, potential funding sources, and guidance in developing methodology.

- Florida CCFA representatives provided contact information for Florida physicians, IBD support group facilitators, and IBD awareness activities.

- Dr. Robert Sandler, Chief, Division of Gastroenterology and Hepatology at the University of North Carolina, and member of CCFA's National Scientific Committee, provided information on IBD epidemiological literature, former IBD study group activities, survey development, and future research development.

- Dr. Amy Trachter, Assistant Professor of Clinical Medicine, Department of Medicine Division of Gastroenterology, Miller School of Medicine University of Miami, provided revisions to patient survey and disseminated surveys to IBD patients. Dr. Trachter also offered additional support for developing grant proposals and future IBD research.

- Dr. Subra Kugathasan, Associate professor, Pediatrics, Medical College of Wisconsin, discussed resources imperative for the development and maintenance of a pediatric IBD registry.

- Dr. Ira Shafran, Shafran Gastroenterology Center, provided the "Inflammatory Bowel Disease Questionnaire Treatment Evaluation Form," a survey administered to patients at the Gastroenterology Center.

- Dr. Lisa Herrinton (Co-PI of IBD study funded by CCFA) of Kaiser Permanente Division of Research, provided information regarding research approach and methodology of two CCFA-funded epidemiological studies. She also shared with DOH the prevalence of IBD among nine health plans across the United States (U.S.), and incidence and prevalence of IBD at Kaiser Permanente, Northern California.

- Mr. David Wolff, Crohn's and Colitis support group facilitator, provided information about IBD patients and the daily implications of living with these illnesses. Mr. Wolff gave insight for the development of a pilot patient survey and assisted in the distribution of surveys to support group members.

Advisory Committee

The study advisory group (a.k.a. Advisory Committee) consisted of epidemiologists at DOH, analysts at AHCA and Blue Cross Blue Shield, physicians and researchers at the University of Florida, members of the House of Representatives and the Senate, representatives from CCFA, medical providers, and other interested groups. The group welcomed any interested organization or individual to participate in the study group.

The first Advisory Committee conference call was held on June 14, 2005. Representatives from the DOH and the University of Florida (UF) participated in the conference call. The group decided to appoint a coordinator, develop an advisory committee, conduct monthly conference calls, and schedule an in-person meeting for advisory members. The group also approved the data collection methodology proposed by the DOH.

Regan Glover of the DOH was appointed as the project coordinator on July 18, 2005.

A letter of invitation to join the Advisory Committee was sent to medical providers, the legislature, representatives from Blue Cross Blue Shield of Florida, state and national Crohn's and Colitis Foundation of America representatives, and the Agency for Health Care Administration. Those interested in joining the committee and/or following the study were placed in a contact database.

Members of the Advisory Committee, consultants, and analysts for this study are:

- AHCA: Gloria Barker, Mel Chang, Susan Chen, Beth Eastman, Adrienne Henderson, Lisa Rawlins, and Cliff Schmidt
- BCBS: John Bookstaver, Randy Kammer, John Montgomery, David Pizzi, and John Williams
- CDC: Sean Cucchi and Siobhan O'Connor
- CCFA: Kiren Annigeri, Marlene Bluestein, Toby Gordon, Marjorie Merrick, Suzanne Rosenthal, Allison Silver, Ellen Shapiro, Kelly Stouten, and Dave Wolff
- DOH: Lisa Fisher, Regan Glover, Youjie Huang, Curt Miller, Heather Murphy, Mike Paredes, and Dian Sharma
- Florida House Representative: Eleanor Sobel
- Florida Senate: Gwen Margolis
- Kaiser Permanente: Lisa Herrinton
- Tidewater Consulting, Inc.: Frank Mayernick
- Physician: Laurence Adams
- Psychologist: Amy Trachter
- UF: Paul Duncan, Chris Jolley, Robert Frank, and John Valentine

Conference calls were held on August 11, September 1, October 6, November 3, 2005, and January 18, 2006. Representatives from a number of agencies, universities, and organizations, as well as interested individuals, participated in the conference calls. The Advisory Committee provided recommendations for the following issues:

- Requirements of House Bill 869.
- Identification of additional members for the study advisory group.
- Plan of study, including overall approach and timeline.
- Diagnoses and procedure codes (ICD-9) for identifying IBD cases in claim data.
- Methods of conducting a survey of GI physicians and IBD patients.
- Development of the pediatric survey and cover letter.
- Survey questions to be added to statewide Behavioral Risk Factor Surveillance System (BRFSS).
- Progress of the study, including data analyses and survey response.
- Preliminary findings of the study.

On November 15, 2005, the Advisory Committee had an in-person meeting in Gainesville, Florida. The participants reviewed preliminary findings and discussed strengths/limitations of study methods and potential sources of data dissemination.

Information Dissemination

The DOH Bureau of Epidemiology made great efforts to disseminate the information regarding the study, including the purpose, methods, and preliminary results to public health professionals, medical providers, Advisory Committee members, and the general public during the entire study period.

- To public health professionals:
  - The Bureau published an article introducing the new research in *Epi Update* in July 2005. *Epi Update* is a web-based weekly journal published by the Bureau of Epidemiology. A follow-up article to update the progress of the study was published in *Epi Update* in September 2005.
  - The study was introduced to county health departments on a bi-weekly conference call in August 2005.
  - An overview of the IBD study was submitted to The Health Advisor, which is the forum to spotlight Department of Health special events, people, programs, and statistics. The newsletter is sent to county health departments, Department of Health units, legislators, and others involved in health around the state and country. The article will appear in the January/February 2006 issue.

- To Advisory Committee members:
  - Plans, progress of the implementation of the study, and preliminary results were provided to, and reviewed by, the Advisory Committee at monthly conference calls and the in-person meeting in November.

- To Medical providers:
  - The study was introduced to gastroenterologists at the 40th Annual Meeting of the Florida Gastroenterological Society and the American College of Gastroenterology in Naples, Florida, on September 9-11, 2005.

- To interested groups and individuals:
  - The project coordinator presented preliminary findings for Crohn's Disease at the CCFA Fourth Annual Advances in IBD Research in Miami Beach, Florida, in December 2005.
  - Per suggestion from a spokesperson for the national chapter of CCFA, a letter was sent to former first lady, Barbara Bush, introducing the Florida IBD study and inviting her to attend a meeting where the findings from this study will be presented.
  - Frequent conversations were maintained via e-mails and phone calls between the project coordinator and IBD support groups in the state.

METHODS

Sources of Data

When sources of population-based data were identified, the DOH research team found that all databases available were developed for purposes other than IBD epidemiologic study, and not a single database was available that would meet the specific needs for this study. Therefore, the

research team decided to collect a number of large databases that each covers part of the IBD population and then combine the information from these databases for a comprehensive result.

The data included in this study consisted of healthcare claim data (hospital discharge data, ambulatory care data, Blue Cross Blue Shield data, and Medicaid data), and survey data (physician survey, patient survey, and BRFSS survey). Collectively, these data covered a majority of the Florida population and provided a well-represented prevalence of IBD in Florida.

Blue Cross Blue Shield (BCBS) claim data

BCBS of Florida provided claim data for their members from calendar years 2001 to 2005. BCBS is one of the major private health insurance carriers, with approximately 30 percent of Florida's commercial market share. More than 2.5 million BCBS members in Florida receive medical services every year. BCBS members consist of males and females of all ages and races. A majority (more than 80 percent) of members who had a claim record are under the age of 65. Claim data capture information on hospitalizations and clinic visits.

The data were unduplicated to provide the number of patients, instead of the number of medical services. Therefore, if a patient with IBD had more than one visit, he or she was only counted once during the data collection timeframe. Disease diagnoses were grouped into several categories: Crohn's disease (ICD-9 code: 555.9), chronic proctitis (556.2), chronic sigmoiditis (556.3), colitis (556.8, 556.9), enteritis (555.0, 555.1), ileitis (555.2), and other and unspecific colitis (558.9). Data were broken down by patient's age, sex, and residential county.

The DOH included data in four years (2001-2004) in this study, with 10,970,547 person-years. On average, 2,742,637 BCBS members were included in the data each year during 2001-2004.

Medicaid data

Medicaid claim data in fiscal years (FYs) 2000-2004 were provided by AHCA. Medicaid data included all claims, both hospitalizations and clinic visits, for more than one million Medicaid recipients in Florida. Medicaid recipients consist of people of all ages, with more than 50 percent of recipients who are under age 20.

The data were unduplicated to count only the number of patients who received medical care. Disease diagnoses were grouped into several categories: Crohn's disease (ICD-9 code: 555), ulcerative colitis (ICD-9 code: 556), and other IBD (ICD-9 code: 558). Data were broken down by patient's age, sex, and residential county.

Data in all five years (FYs 2000-2004) were included in the study. The data contain 5,922,697 person-years of records, with an average of 1,184,539 recipients each year.

Ambulatory patient data

AHCA provided ambulatory patient data for fiscal years1997-2004. The ambulatory patient data are collected from freestanding ambulatory surgical centers, lithotripsy centers, cardiac catheterization laboratories, and short-term acute care hospitals. Ambulatory patients are those who have a face-to-face encounter with a provider, and who are not formally admitted

as an inpatient in an acute care hospital setting, and not treated in the emergency room. The ambulatory patient data include patients of all ages and races, regardless of the type of a patient's medical insurance.

Disease diagnoses were grouped into several categories based on either primary diagnosis or any of the secondary diagnoses. These categories are Crohn's disease, ulcerative colitis, and other colitis.

Data in all eight years were included in the analysis. There were 12,710,291 patient records analyzed, with an average of approximately 1.6 million patients every year. Patients might have more than one ambulatory visit either in a single year or in different years. The DOH unduplicated multiple visits in two ways: 1) to count each patient only once for the entire 8-year period for number of "new" IBD patients among ambulatory patients; and 2) to count each patient once in a single year for an annual prevalence of IBD patients among ambulatory patients. Data were analyzed by race, age, residential county, and type of medical insurance.

Hospital discharge data

AHCA also provided hospital discharge data for 1995-2004. The hospital discharge data include all inpatients of all ages and types of medical insurance.

Disease diagnoses were grouped into several categories based on either primary or secondary diagnoses. These categories are Crohn's disease, ulcerative colitis, and other colitis.

Data in all 10 years were included in the analysis. There were 12,769,086 inpatient records analyzed, with an average of approximately 1.2 million patients every year. Many patients had more than one hospitalization either in a single year or in different years. The DOH unduplicated multiple hospitalizations in two ways: 1) to count each patient once in the entire 10-year period for number of "new" IBD patients among inpatients; and 2) to count each patient once in a single year for an annual prevalence of IBD patients among inpatients.

IBD inpatients who had ambulatory visit(s) were excluded from the analyses to avoid duplication for patients receiving medical care in hospitals. Data were analyzed by race, age, residential county, and type of medical insurance.

Gastroenterology (GI) Physician survey

DOH Bureau of Epidemiology developed a gastroenterology (GI) physician survey in August 2005. (See attachment 1 for the survey questionnaire.) The survey was designed to estimate:

- Patient demographics
- Number of newly diagnosed IBD cases within past 12 months
- Severity of illness measured by hospitalizations due to IBD
- Role of family history
- Patient's enrollment for colon cancer surveillance

The survey questionnaire was sent to 660 gastroenterologists in Florida by mail. The DOH research team received 132 returned survey questionnaires, among which 113 were completed.

Regan Glover, the project coordinator, distributed the survey questionnaires at the general sessions of the 40th Annual Meeting of the Florida Gastroenterological Society and the American College of Gastroenterology in Naples Florida on September 9-11, 2005. Ten completed surveys were received from the conference attendees.

Pediatric GI physician survey

The Bureau of Epidemiology revised the GI-physician survey questionnaire to address pediatric IBD patients seen by pediatric specialists. Data collected were similar to that collected from the GI physician survey. Survey questionnaires were distributed to 41 Florida members of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) via mail. A cover letter and pre-paid return envelope were included with the mailed survey. Collection period began September 26, 2005, and ended on October 26, 2005. Eight (20 percent) of 41 physicians returned completed survey questionnaires.

IBD patient survey

The DOH team developed a short anonymous survey of IBD patients. (See attachment 2 for the questionnaire.) Dr. Amy Trachter and GI physicians assisted with the design of questionnaire. The purpose of this survey was to obtain information on risk factors of IBD, particularly environmental factors and genetic factors.

The survey was implemented from December 23, 2005, to January 10, 2006. To keep responses anonymous, the DOH did not disseminate directly surveys to IBD patients. Instead, the survey questionnaire was emailed to facilitators of eight CCFA support groups. The facilitators were asked to distribute the survey questionnaire to their group members though e-mails. The total number of IBD patients who received the questionnaire from their support group facilitator was unknown. IBD patients who were willing to participate in the survey completed survey and returned surveys to DOH either electronically (e-mail/fax), or by U.S. Postal Service. The DOH received 27 completed survey questionnaires from IBD patients with two support groups in Miami and Sarasota.

Behavioral Risk Factor Surveillance System survey

The Behavioral Risk Factor Surveillance System (BRFSS) survey is a statewide random telephone survey of civilian, non-institutionalized adults (age 18 and older). The BRFSS is an ongoing collaborative survey with the CDC to monitor trends in risk behaviors related to preventable chronic diseases and conditions in Florida. Respondents are asked about health status, health behaviors, use of screening services, and access to health insurance and health care.

Three questions were designed by the Bureau of Epidemiology to survey the general population. These questions are:

- (Q1) Has anyone, including yourself, in your household, ever been told by a doctor or other health professional that you have Crohn's disease or ulcerative colitis?

- (Q2) How many people in your household have been told that they have Crohn's disease or ulcerative colitis?
- (Q3) How many of these people have been admitted to a hospital in the past 12 months because of Crohn's disease or ulcerative colitis?

The purpose of these questions is to assess the prevalence of IBD (Q1), familial aggregation of IBD cases (Q2), and severity of IBD (Q3) among general population. These questions were included in the BRFSS survey from September 1, 2005, through December 15, 2005. There were 1,847 individuals surveyed, among whom 1,678 responded to these three questions.

Medicare data were requested in October 2005; however, approval to use those records was not received as of the date of this report.

Definition of IBD

The following are the International Classification of Disease Version 9 (ICD-9) codes that were used to define Crohn's disease, ulcerative colitis, and other IBD in healthcare claim data:

Crohn's disease:

555.0: Ileitis (regional, segmental) and Regional enteritis or Crohn's disease of duodenum, ileum, or jejunum
555.1: Colitis (granulmatous, regional, or transmural) and regional enteritis or Crohn's disease of colon, large bowel, or rectum
555.2: Ileitis
555.9: Crohn's disease NOS

Ulcerative Colitis:

556.0: Ulcerative (chronic) enterocolitis
556.1: Ulcerative (chronic) ilecocolitis
556.2: Ulcerative (chronic) proctitis
556.3: Ulcerative (chronic) proctosigmoiditis
556.5: Left-sided ulcerative (chronic) colitis
556.6: Universal ulcerative (chronic) colitis
556.8: Other ulcerative colitis
556.9: Ulcerative colitis, unspecified.

Other IBD:

558.9: Other and unspecified (noninfectious gastroenteritis and colitis)

Procedure code:

45.23: Colonoscopy

Analysis

The primary purpose of analysis was to identify prevalence of IBD, patients' characteristics, and IBD related risk factors. The DOH team did not attempt to make comparisons of prevalence among subpopulations. Therefore, the team did not conduct any statistical tests for difference

in prevalence among subpopulations, nor to adjust prevalence by age-distribution of the population. The methods that the DOH used for this study were:

1. Claim data
   a. Numbers of patients with IBD were tabulated.
   b. Prevalence of IBD was estimated in various populations. Prevalence is the proportion of the population with IBD in a specific year. The prevalence was calculated as follows:
      i. BCBS data and Medicaid data: by sex and age
      ii. Hospital discharge data and ambulatory patient data: by sex, age, race, and ethnicity, and type of insurance
   c. Incidence of IBD was estimated for BCBS IBD patients. Incidence is the number of new cases diagnosed per 100,000 persons in a year. Although BCBS data counted only new patients to the BCBS system in the four-year period, some of "new" patients might have been diagnosed before the study period.
   d. Proportion of IBD patients with a colonoscopy was calculated.

2. BRFSS survey data
   Prevalence of IBD was estimated by race and household income. The prevalence was not weighted by the probability of respondents being selected for the survey because the weight variable was not available during preparation of this report. Responses of "don't know" or "unsure" were excluded from analyses.
3. Physician survey
   Percents of responses were tabulated for estimates of:
   a. Newly diagnosed cases (within past 12 months)
   b. Patient demographics
   c. Severity of illness (hospitalizations)
   d. Role of family history
   e. Colon cancer surveillance

4. Patient survey
   Percents of responses were tabulated for estimates of:
   a. Patient demographics (sex, race/ethnicity and region)
   b. Age of diagnosis/time lived with IBD
   c. Type of IBD (Crohn's disease and ulcerative colitis)
   d. Severity of symptoms (mild, moderate, severe)
   e. Presence of family history
   f. Risk behaviors (active or passive inhalation of cigarette smoke)
   g. General assessment of health

There was a close collaboration among BCBS, AHCA, and DOH representatives and data analysts for this study. John Montgomery, John Williams, and John Bookstaver provided information on BCBS and conducted analyses of BCBS claim data. AHCA representatives Mel Chang, Beth Eastman, Susan Chen, Gloria Barker, Adrienne Henderson, and Cliff Schmidt provided support and conducted analyses on Medicaid data, hospital discharge data, and ambulatory patient data. DOH epidemiologist Youjie Huang and health data analyst Curt Miller analyzed the survey data and conducted part of the analyses of hospital discharge data and ambulatory patient data.

RESULTS

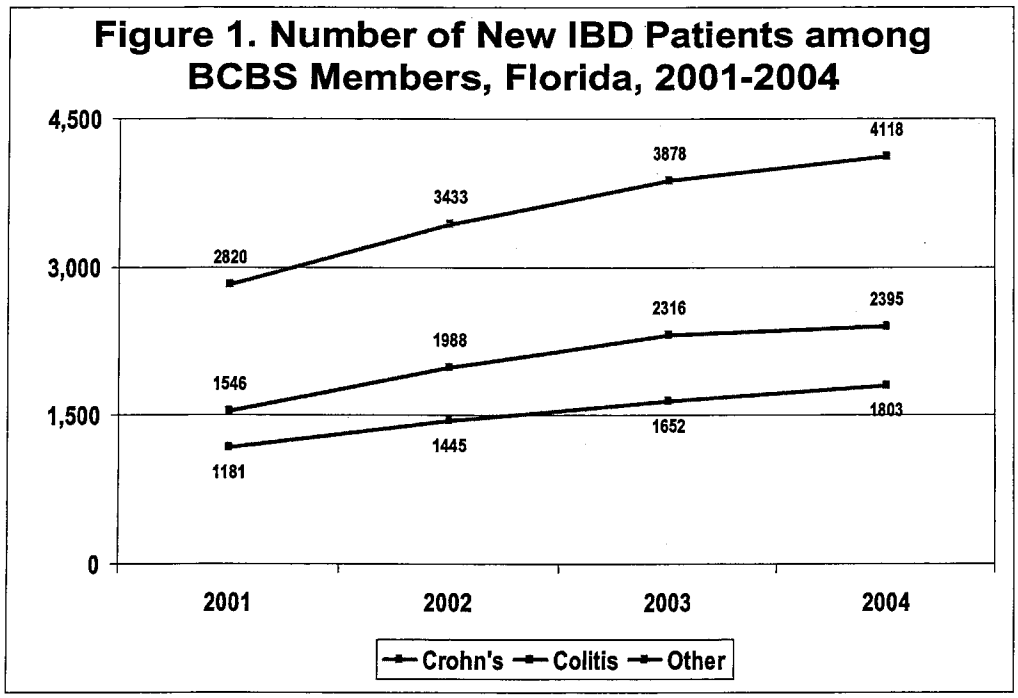
BCBS data

During 2001-2004, 6,373 BCBS members were diagnosed with Crohn's disease and 8,658 were diagnosed with ulcerative colitis. In the BCBS claim data, an average of 2,742,637 BCBS members per year received medical services. Among those members, 1,520 members, on average, were diagnosed with Crohn's disease and 2,061 were diagnosed with ulcerative colitis per year. (Table 1)

Table 1. Average Number of BCBS Members with IBD per Year, Florida, 2001-2004

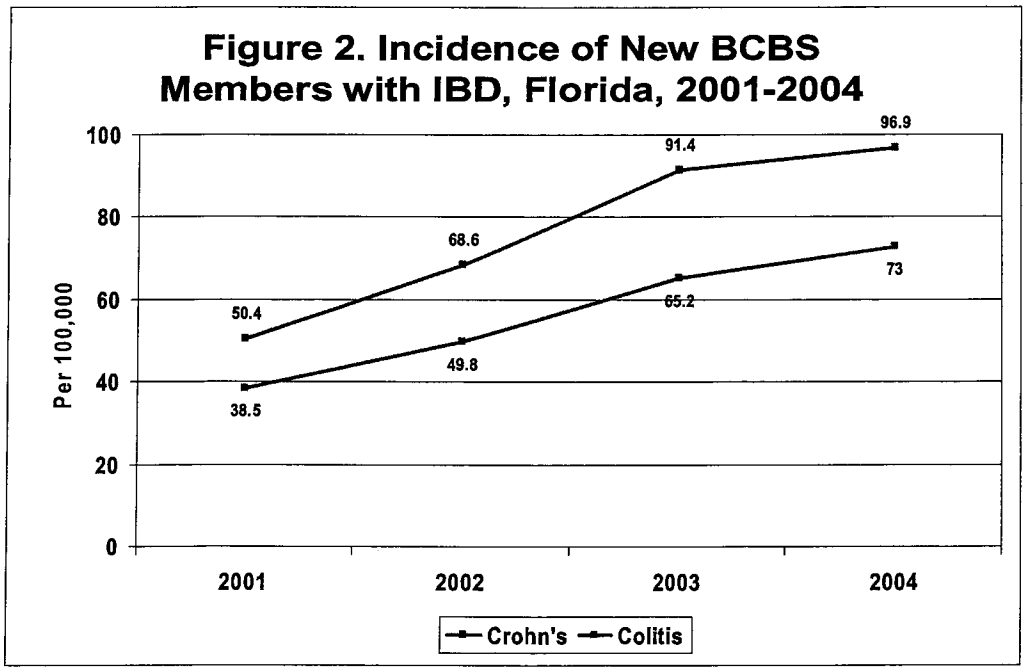
	All IBD	Crohn's	Colitis	Other	# of Members
Total	**7,144**	**1,520**	**2,061**	**3,563**	**2,742,637**
By Age Group					
1-10	**25**	**7**	**9**	**10**	**289,104**
11-20	**196**	**81**	**48**	**68**	**431,765**
21-30	**472**	**150**	**131**	**180**	**350,594**
31-40	**841**	**234**	**258**	**349**	**352,003**
41-50	**1,231**	**287**	**381**	**563**	**398,637**
51-60	**1,464**	**305**	**420**	**738**	**370,815**
61-70	**1,294**	**222**	**388**	**684**	**256,748**
71-80	**1,144**	**156**	**311**	**677**	**170,573**
81+	**430**	**59**	**102**	**269**	**122,395**
By Sex					
Male	**3,006**	**684**	**956**	**1,365**	**1,296,831**
Female	**4,091**	**826**	**1,092**	**2,173**	**1,445,806**

Number of members who were first time diagnosed with Crohn's disease increased by 55 percent from 1,546 in 2001, to 2,395 in 2004. Similarly, the number of members diagnosed with ulcerative colitis increased by 53 percent from 1,181 in 2001, to 1,803 in 2004, and the number of patients diagnosed with other colitis increased by 45 percent from 2,820 in 2001, to 4,118 in 2004 (Figure 1).



The overall four-year prevalence was 222 per 100,000 persons for Crohn's disease, 301 per 100,000 persons for ulcerative colitis, and 520 per 100,000 persons for other IBD.

The incidence (number of new patients among 100,000 people at risk in a year) increased during the four-year period. For Crohn's disease, the rate increased by 92 percent from 50.4 per 100,000 to 96.9 per 100,000 person. The prevalence of ulcerative colitis increased by 90 percent. (Figure 2)

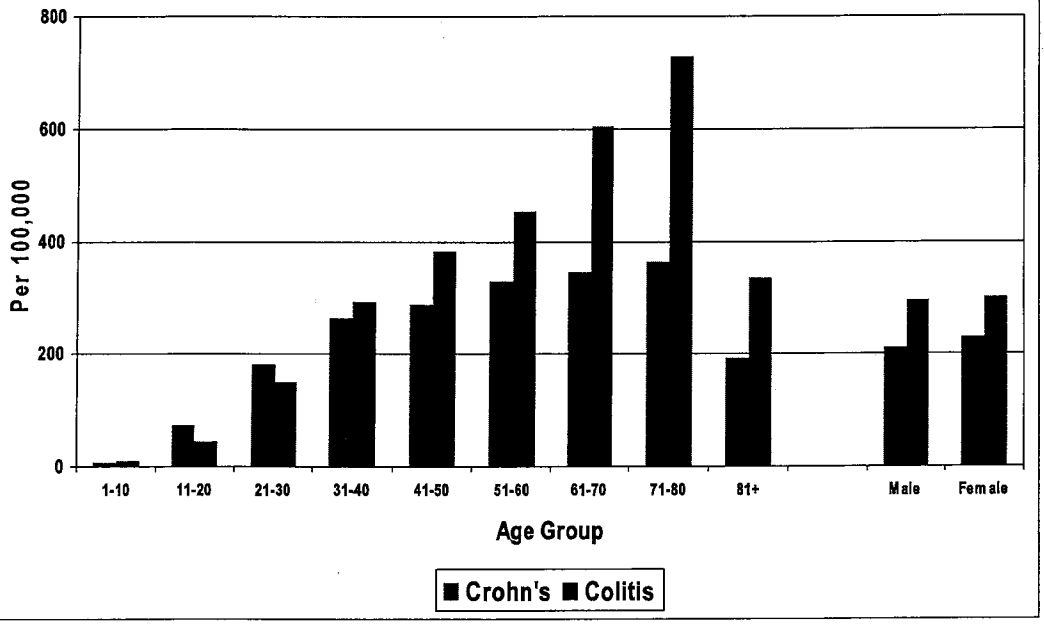


During the four-year period, the number of patients diagnosed with Crohn's disease and ulcerative colitis increased by age, and reached a peak in the 51-to-60–year-old age group (Table 1).

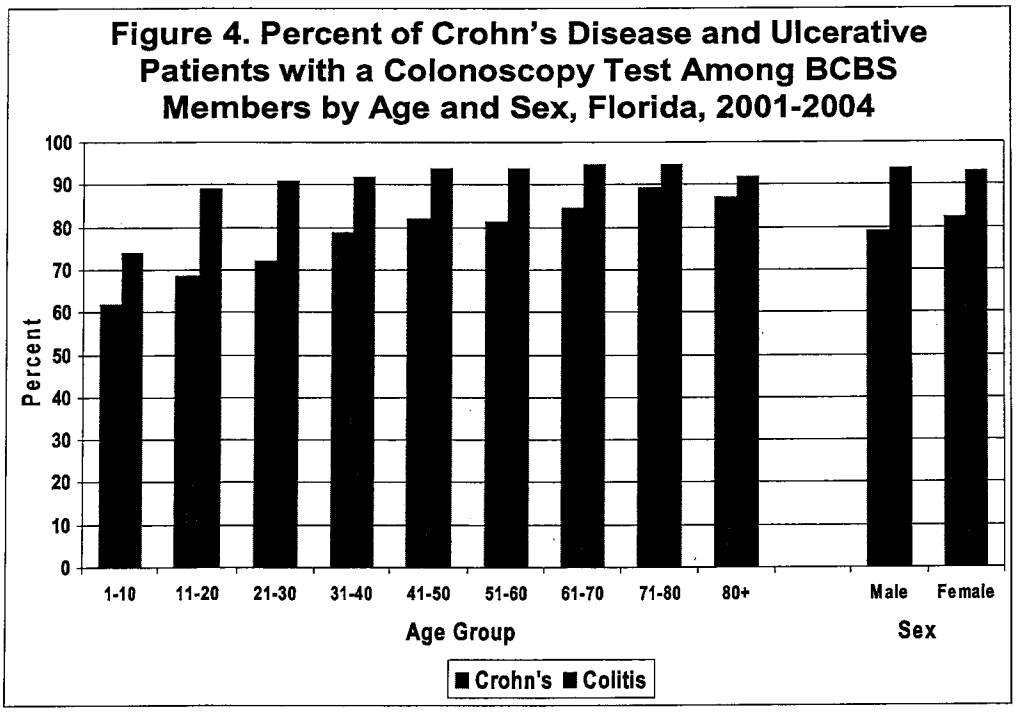
The four-year prevalence was the highest among people between the ages of 71 and 80 years. The prevalence increased by age, except among people age 81 years and older. (Figure 3)

The prevalence was slightly higher among females than among males for Crohn's disease (229 per 100,000 people versus 211 per 100,000 people), and ulcerative colitis (302 per 100,000 people versus 295 per 100,000 people). (Figure 3)

Figure 3. Prevalence of Crohn's Disease and Ulcerative Colitis among BCBS Members By Age and Sex, Florida, 2001-2004



A colonoscopy is a medical procedure that is required to confirm the diagnosis of Crohn's disease and ulcerative colitis. Among BCBS members, a majority of new patients with Crohn's disease and ulcerative colitis had a colonoscopy. The percent of Crohn's disease patients who had a colonoscopy increased by age, from 61 percent among patients under age 11, to 87 percent among patients aged 80 years and older. The percent of patients with a colonoscopy was higher among ulcerative colitis patients than among Crohn's disease patients. Ninety percent of patients with ulcerative colitis had a colonoscopy with the exception of patients under age 11. (Figure 4)



Among Crohn's disease patients, more females (82 percent) had a colonoscopy than did males (79 percent). Among ulcerative colitis patients, 93 percent of both males and females had a colonoscopy.

Among BCBS members, the prevalence of Crohn's disease was greater than 400 per 100,000 in Liberty, Wakulla, Jefferson, Brevard, Glades, and Lee counties. (Figure 5) Liberty, Wakulla, Leon, Columbia, Brevard, Glades, Orange, Hillsborough, Polk, Sarasota, Palm Beach, and Broward counties had a prevalence of ulcerative colitis greater than 400 per 100,000 people. (Figure 6) Liberty, Wakulla, Brevard, and Glades counties had a high prevalence for both Crohn's disease and ulcerative colitis.

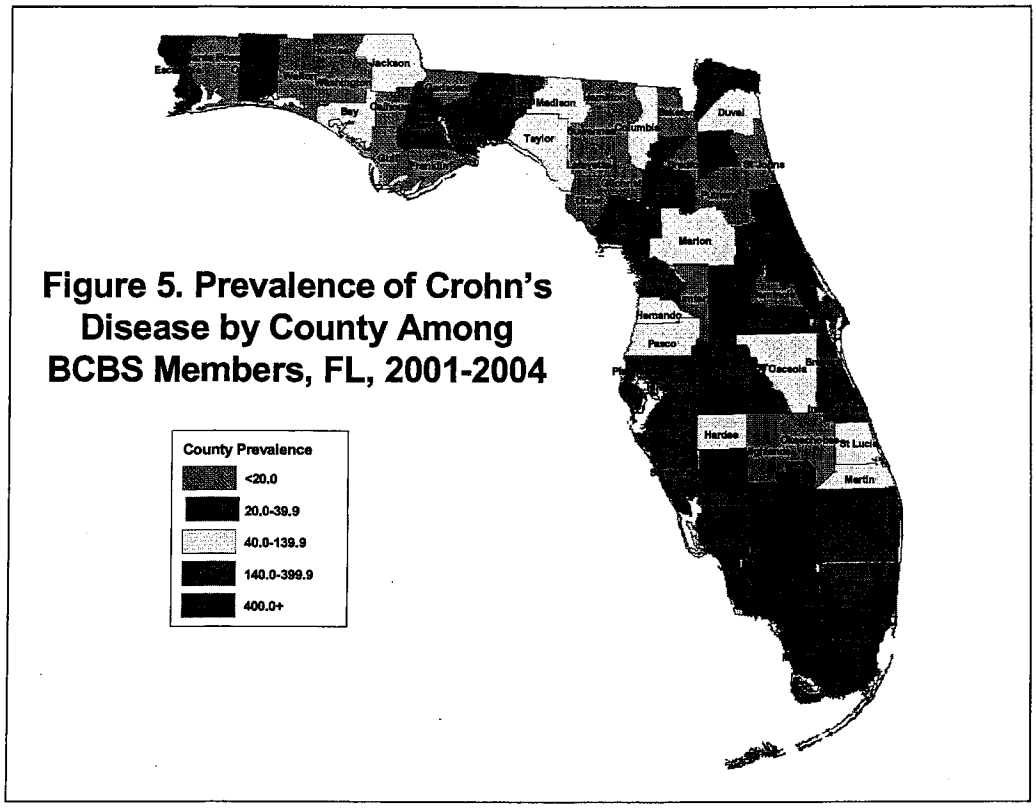


Figure 5. Prevalence of Crohn's Disease by County Among BCBS Members, FL, 2001-2004

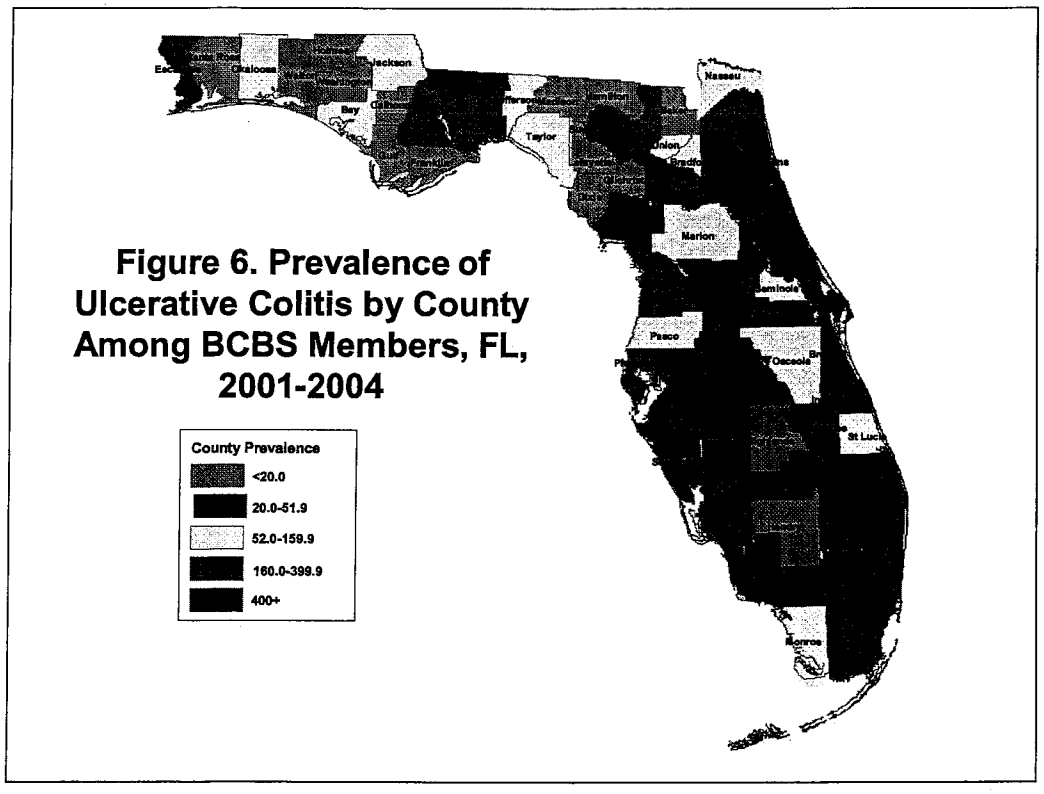


Figure 6. Prevalence of Ulcerative Colitis by County Among BCBS Members, FL, 2001-2004

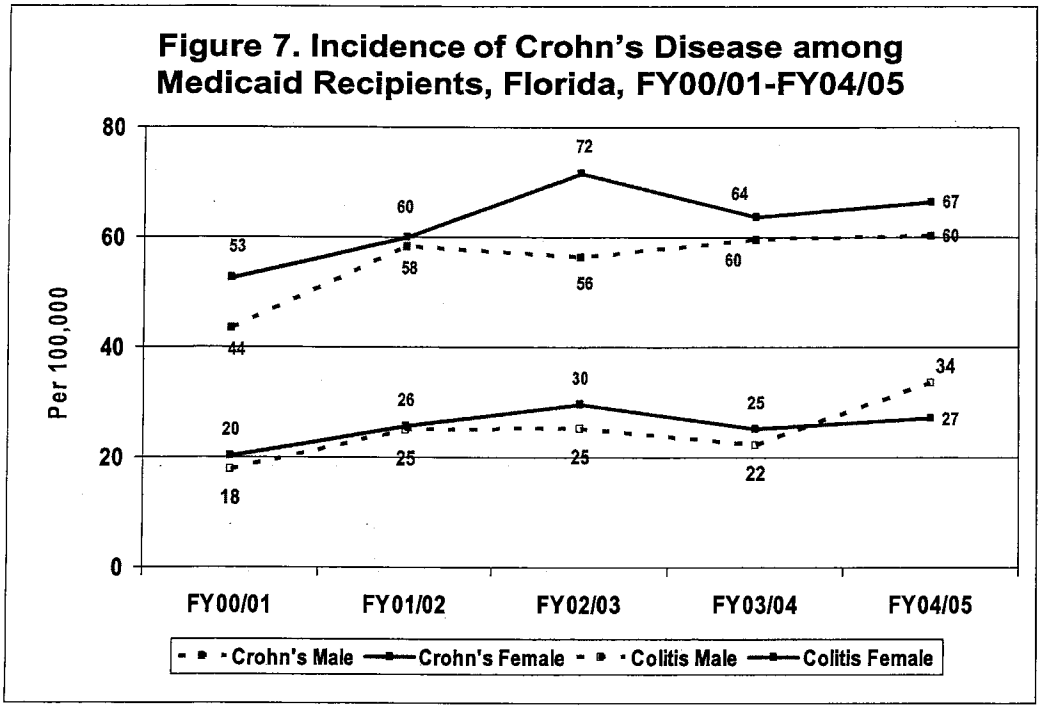
Medicaid data

The number of Medicaid recipients receiving medical service varied greatly during FY 2000-2001 through FY 2004-2005. The average number of recipients with at least one claim for medical service was 1,184,535 per year. The average number of Medicaid recipients diagnosed with Crohn's disease per year was 717 patients, with a prevalence of 61 per 100,000 people. On average, 304 recipients per year were diagnosed with ulcerative colitis, with a prevalence of 26 per 100,000 people. The number of recipients diagnosed with other colitis was 26,055 per year with a prevalence of 2,200 per 100,000 people. (Table 2)

Tables 2. Number of Patients with IBD among Medicaid Recipients, Florida, FY00/01-FY04/05

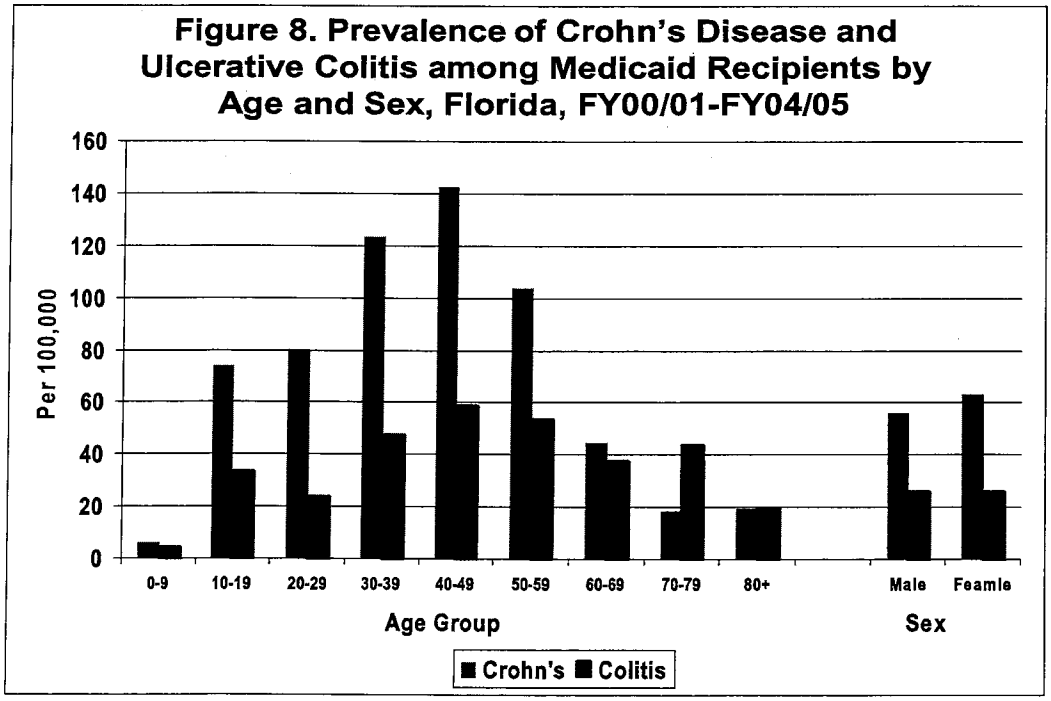
	FY00/01	FY01/2	FY02/3	FY03/4	FY04/5
# of Recipients	**1,042,369**	**1,084,413**	**895,044**	**1,170,599**	**1,730,249**
Crohn's Disease					
Total	**513**	**644**	**590**	**728**	**1,111**
Female	**348**	**416**	**406**	**474**	**733**
Male	**165**	**228**	**184**	**254**	**378**
Ulcerative Colitis					
Total	**202**	**275**	**250**	**283**	**510**
Female	**134**	**177**	**168**	**188**	**300**
Male	**68**	**98**	**82**	**95**	**210**
Other					
Total	**25,966**	**20,785**	**18,755**	**27,360**	**37,411**
Female	**13,863**	**10,990**	**9,928**	**14,317**	**20,076**
Male	**12,101**	**9,793**	**8,824**	**13,038**	**17,333**

The prevalence of both Crohn's disease and ulcerative colitis increased during FY2000-2001 through FY2004-2005. The prevalence of Crohn's disease increased by 30 percent (38 percent for males and 27 percent for females), and the prevalence of ulcerative colitis increased by 52 percent (87 for males and 35 percent for females). (Figure 7)



The age-specific prevalence was the highest among people between ages 40 and 49 for both Crohn's disease (142 per 100,000 persons) and ulcerative colitis (58 per 100,000 persons).

Females had a higher prevalence of Crohn's disease (63 per 100,000 persons) than males (56 per 100,000 persons). However, the prevalence of ulcerative colitis was the same (26 per 100,000 persons) among both males and females. (Figure 8)



Hospital discharge data

There were 12,769,086 patients discharged from hospitals during 1995-2004. During this period, 187,700 patients were diagnosed with IBD, among whom 15,340 had Crohn's disease and 13,820 had ulcerative colitis.

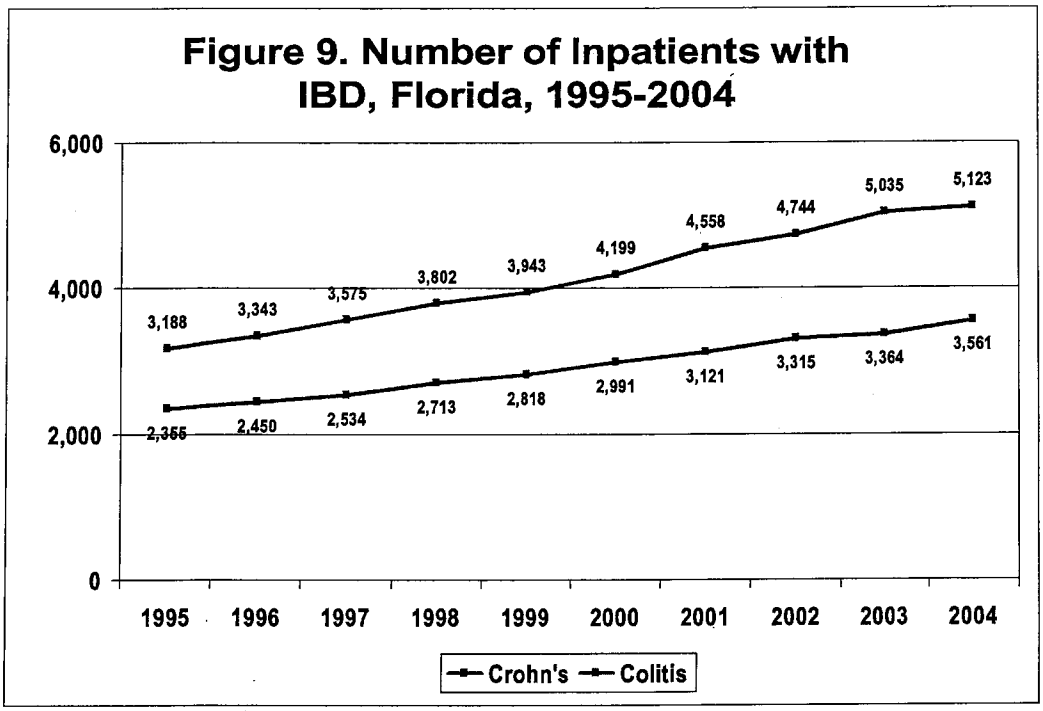
Among patients with Crohn's disease and ulcerative colitis, there were more female patients, than there were male patients. Although most Crohn's disease and ulcerative colitis patients were Whites, many patients of other races/ethnicities were diagnosed with IBD as well. (Table 3)

Table 3. Average Number of New Patients Hospitalized with IBD per Year, Florida, 1995-2004

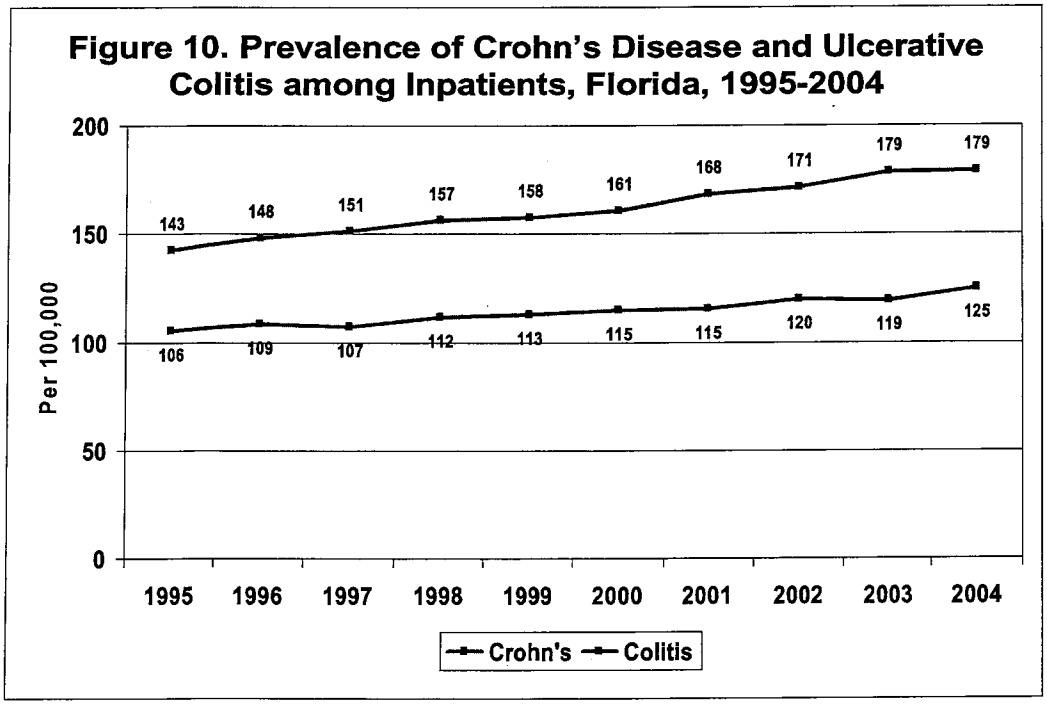
	All IBD	Crohn's	Colitis	Other		All IBD	Crohn's	Colitis	Other
Total	18770	1534	1382	16314					
By Age					By Race				
0-	246	0	0	246	Black	2,186	92	90	2,039
1-10	1,129	5	3	1,123	Hispanic	2,424	90	117	2,256
11-20	534	60	30	456	Other	442	35	34	383
21-30	1,193	158	83	987	White	13,718	1,318	1,140	11,635
31-40	1,946	227	141	1,638	By Insurance				
41-50	2,207	237	152	1,882	No Insurance	1,265	141	72	1,083
51-60	2,156	217	177	1,821	Medicare	8,899	602	741	7,788
61-70	2,708	231	232	2,309	Medicaid	2,120	95	71	1,993
71-80	3,673	260	331	3,172	Private	6,052	646	463	5,090
81+	2,980	139	231	2,681	Other	433	50	35	361
By Sex									
Male	7,134	662	600	6,049					
Female	116,356	872	782	10,265					

New patients, excluding patients who were diagnosed as outpatients

The number of patients with Crohn's disease and ulcerative colitis that were hospitalized increased by 61 percent and 51 percent, respectively, from 1995 to 2004. In 2004, 5,123 Crohn's disease and 3,561 ulcerative colitis patients were hospitalized. (Figure 9)
The 10-year overall prevalence was 120.1 per 100,000 people for Crohn's disease and 108.2 per 100,000 people for ulcerative colitis during the 10-year period. For calculating overall prevalence, a patient with an IBD diagnosis was counted once, regardless of how many times the patient was hospitalized in the 10-year period. Some patients were diagnosed with both Crohn's disease and ulcerative colitis. The average prevalence of patients with either Crohn's disease and/or ulcerative colitis was 221.0 per 100,000 people among inpatients.

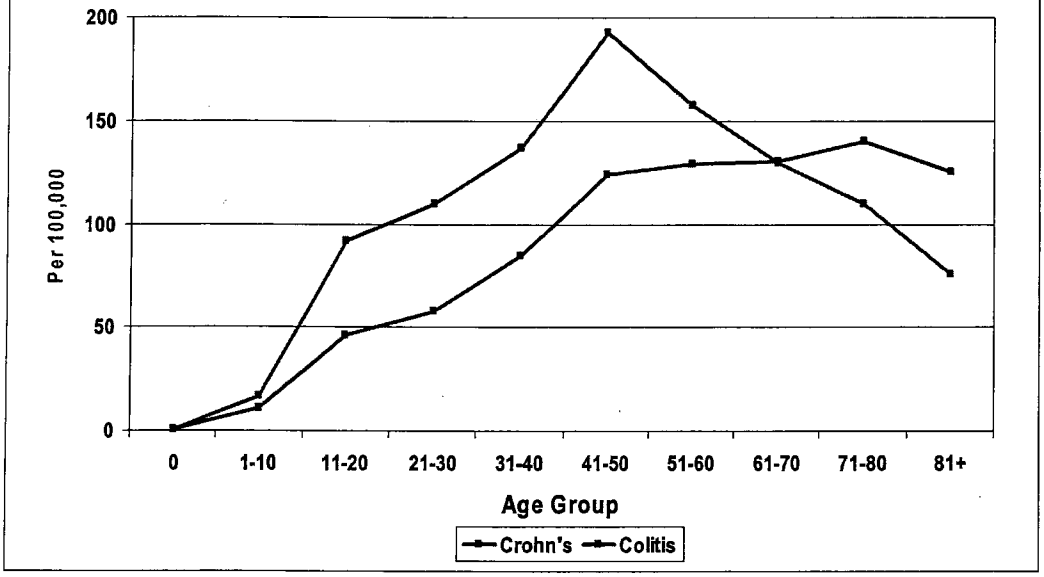


The annual prevalence of Crohn's disease increased by 26 percent, from 143 per 100,000 people in 1995 to 179 per 100,000 people in 2004. The annual prevalence of ulcerative colitis increased by 18 percent, from 106 per 100,000 persons in 1995 to 125 per 100,000 persons in 2004. (Figure 10)



The age-specific prevalence of Crohn's disease increased by age, reached a peak of 193 per 100,000 people among the 41-to-50-year age group, then it decreased to 76 per 100,000 people among people aged 81 years and older. The prevalence of ulcerative colitis also increased by age, reached a peak of 140 per 100,000 people among 41-to-50 year age group, and decreased to 125 per 100,000 people among people aged 81 years and older. (Figure 11)

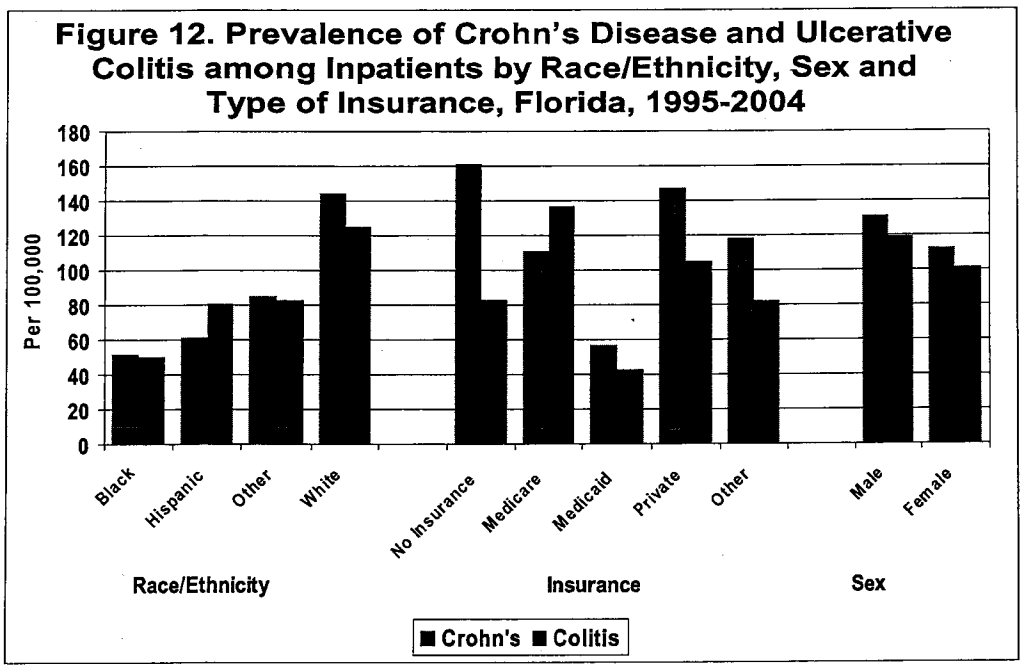
Figure 11. Prevalence of Crohn's Disease and Ulcerative Colitis among Inpatients by Age Group, Florida, 1995-2004



Whites had the highest prevalence of Crohn's disease (145 per 100,000 people) and ulcerative colitis (125 per 100,000 people) among four race/ethnicity groups. Blacks had the lowest prevalence for both Crohn's disease (61 per 100,000 people) and ulcerative colitis (51 per 100,000 people).

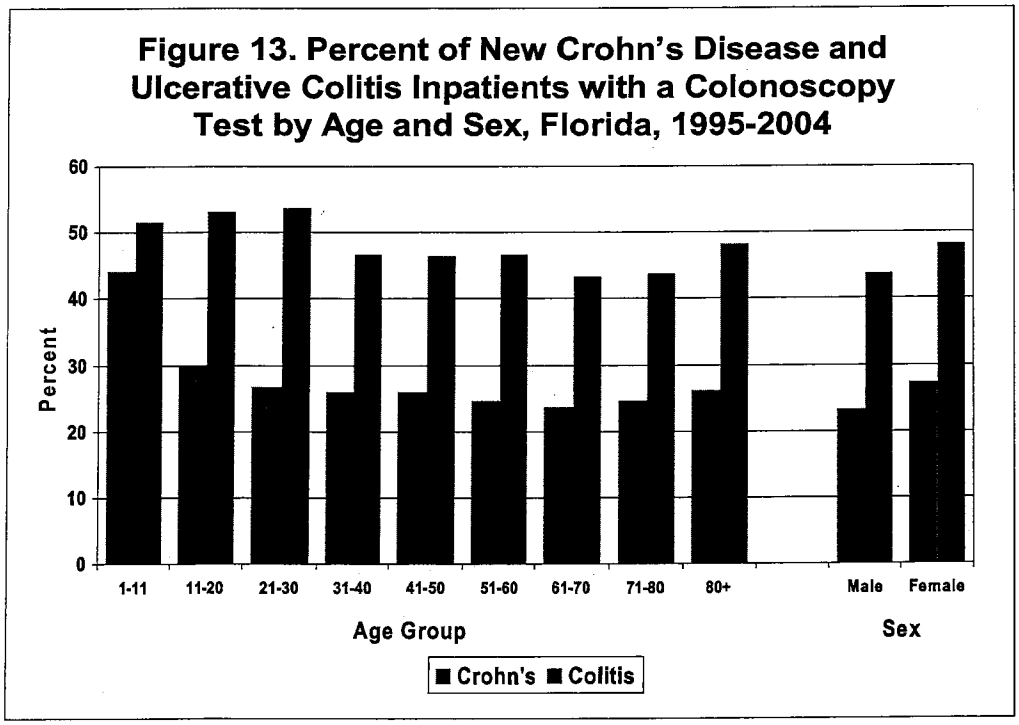
Patients who had a private medical insurance (147 per 100,000 people) and patients without any insurance (162 per 100,000 people) had a higher prevalence for Crohn's disease than their counterparts did. Medicare beneficiaries had the highest prevalence (137 per 100,000 people) of ulcerative colitis. Medicaid recipients had the lowest prevalence of both Crohn's disease (57 per 100,000 people) and ulcerative colitis (43 per 100,000 people).

Males had a higher prevalence of both Crohn's disease (131 per 100,000 people versus 113 per 100,000 people) and ulcerative colitis (119 per 100,000 people versus 101 per 100,000 people) than females. (Figure 12)

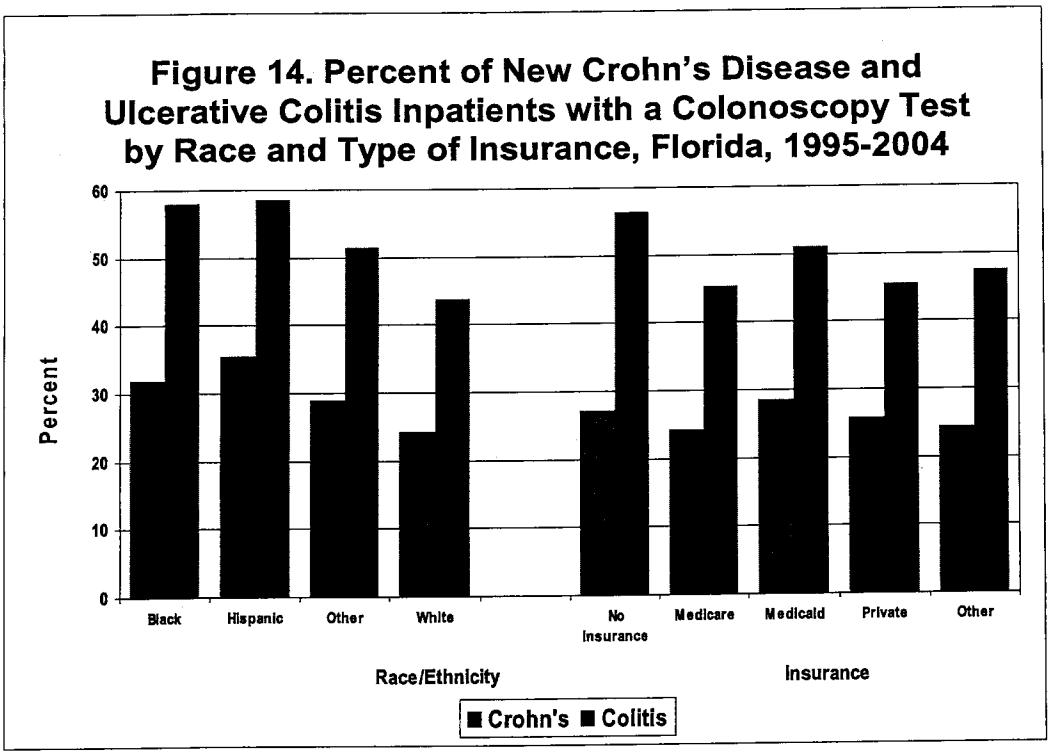


Approximately one quarter (25.5 percent) of new Crohn's disease patients had a colonoscopy. The percent of patients with a colonoscopy was higher among younger patients (under age 20) than among older patients, and higher among females than among males.

Among new patients with ulcerative colitis, 42.3 percent had a colonoscopy. The percent of patients with a colonoscopy was also higher among patients under age 30 and among females than among their counterparts. (Figure 13)



The percent of new Crohn's disease patients with a colonoscopy was the highest among Hispanics. Both Medicaid recipients and patients without any medical insurance had a higher percent than their counterparts did. The percent of new ulcerative colitis patients with a colonoscopy was higher among Hispanics and Blacks than Whites and people of other races. The percent of ulcerative colitis patients with a colonoscopy was also higher among people without medical insurance and Medicaid recipients than for people with a private insurance and Medicare beneficiaries. (Figure 14)



Twelve counties had a 10-year overall prevalence of Crohn's disease of 124 per 100,000 people or greater in Florida. These counties are Holmes, Union, Seminole, Hernando, Pasco, Pinellas, Indian River, Okeechobee, Sarasota, Charlotte, Collier, and Monroe. (Figure 15)

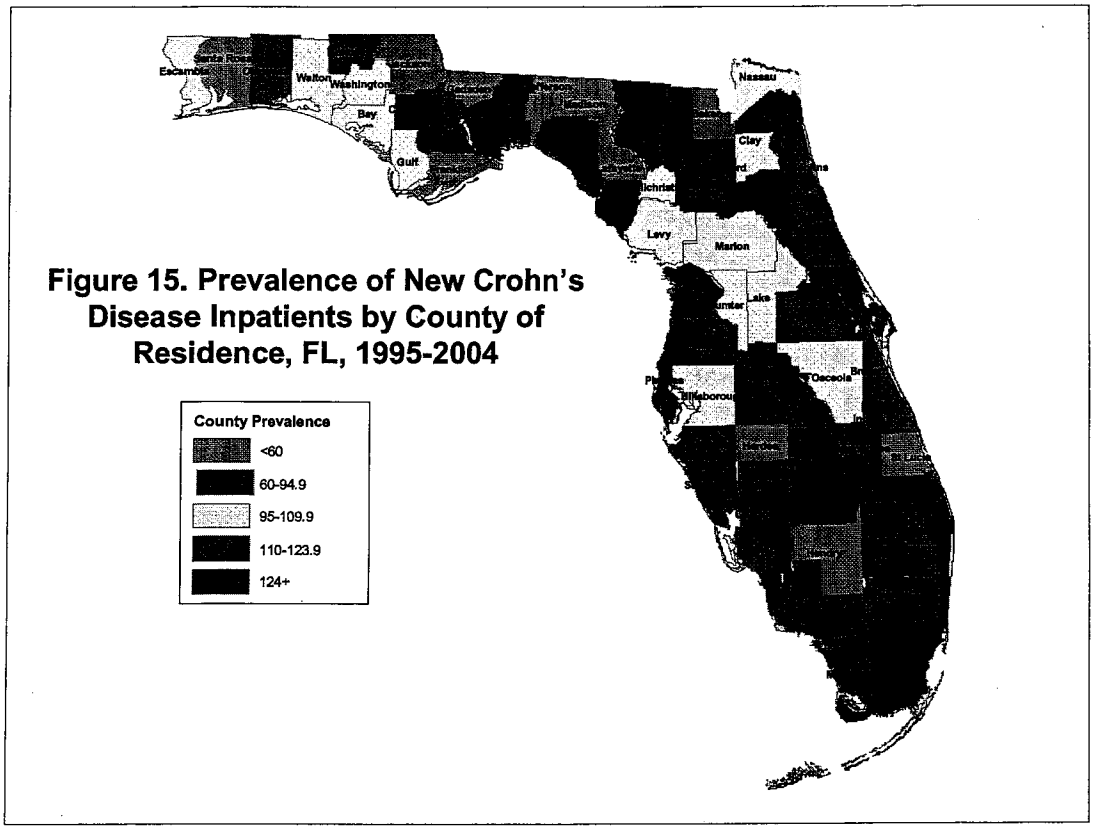
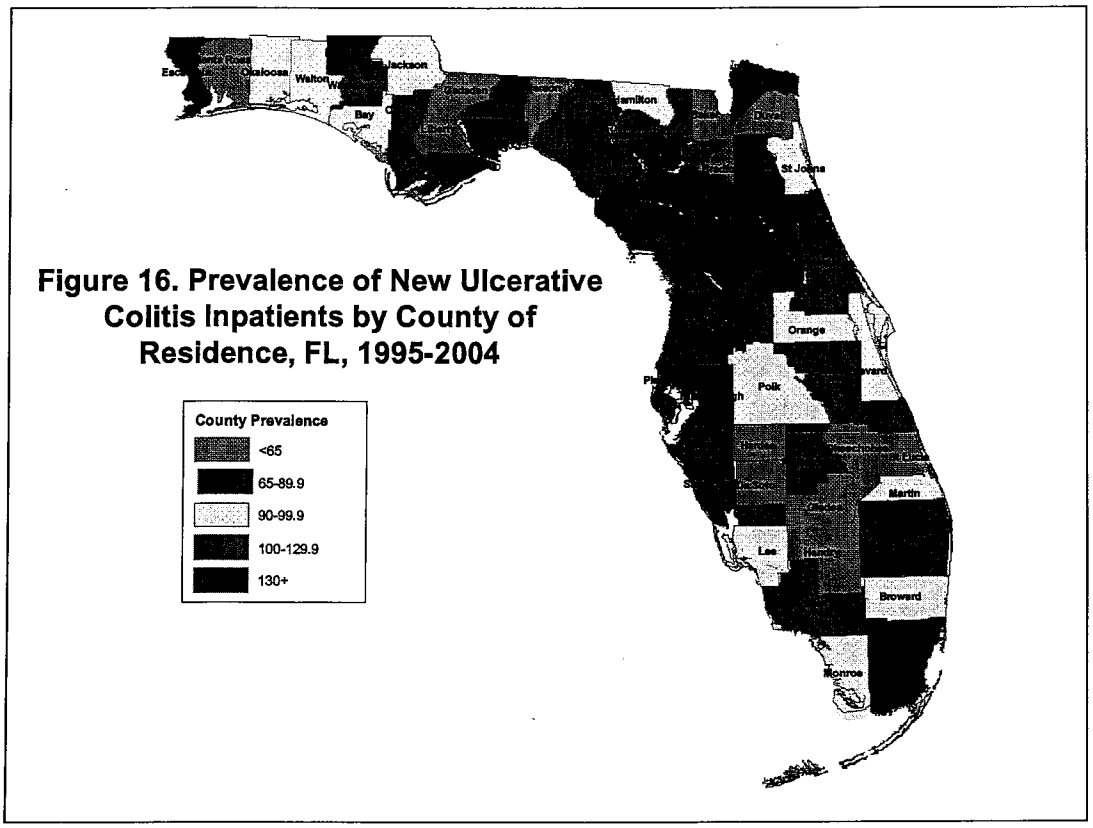


Figure 15. Prevalence of New Crohn's Disease Inpatients by County of Residence, FL, 1995-2004

Twelve counties had a prevalence of ulcerative colitis of 130 per 100,000 or greater in Florida. These counties are Gulf, Suwannee, Columbia, Union, Citrus, Sumter, Lake, Hernando, Osceola, Sarasota, Charlotte, and Collier. (Figure 16)

Union, Hernando, Sarasota, Charlotte, and Collier had higher prevalence rates for both Crohn's disease and ulcerative colitis than other counties in Florida during 1995-2004.



Ambulatory patient data

There were 12,710,291 patients who received at least one ambulatory care service during 1997-2004. Among these patients, 22,005 were diagnosed with Crohn's disease, 32,541 were diagnosed with ulcerative colitis, and 120,138 were diagnosed with other colitis.

There were more females than males among patients with Crohn's disease and ulcerative colitis. Approximately 80 percent of Crohn's disease and ulcerative colitis patients were White, and 60 percent of patients had a private health insurance. (Table 4)

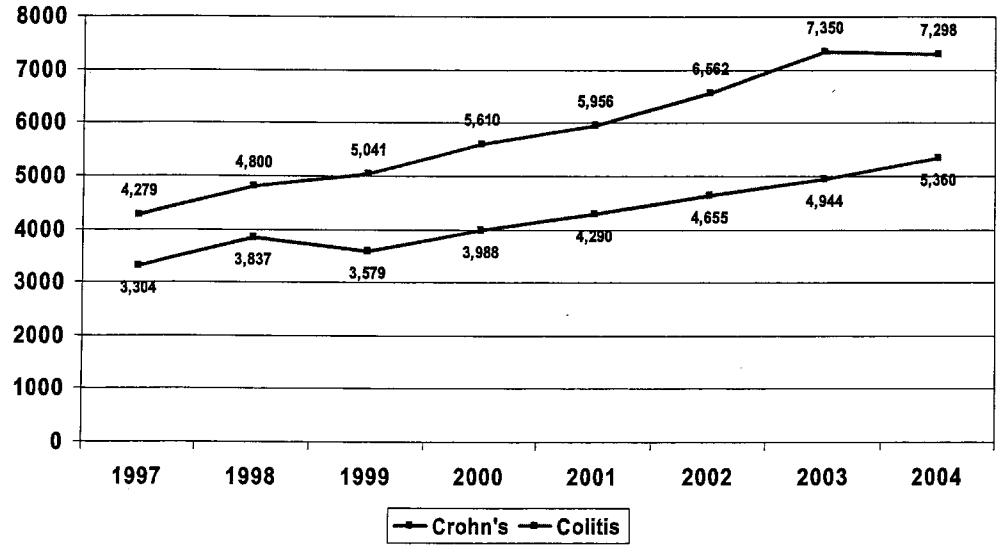
Table 4. Average Number of New Outpatients with IBD per Year, Florida, 1997-2004

	All IBD	Crohn's	Colitis	Other		All IBD	Crohn's	Colitis	Other
Total	20,143	2,751	4,068	15,017					
By Age					By Race				
0-	28	1	3	27	Black	950	111	186	729
1-10	123	11	11	105	Hispanic	1,492	142	268	1,196
11-20	503	135	115	314	Other	1,583	292	382	1,007
21-30	1,323	300	327	837	Whites	16,117	2,207	3,232	12,085
31-40	2,374	439	595	1,588	By Insurance				
41-50	3,185	498	707	2,284	No Insurance	509	77	100	366
51-60	3,697	494	706	2,803	Medicare	7,337	756	1,291	5,815
61-70	3,836	423	710	2,992	Medicaid	629	91	88	490
71-80	3,768	348	679	3,004	Private	11,100	1,726	2,446	7982
81+	1,306	105	218	1,064	Other	568	101	142	363
By Sex									
Male	8,151	1,180	1,915	5,829					
Female	11,993	1,571	2,153	9,189					

New patients, including patients who were also hospitalized

The number of Crohn's disease patients that were treated as ambulatory patients was 3,304 in 1997 and increased by 62 percent to 5,360 in 2004. The number of ulcerative colitis patients increased by 71 percent, from 4,279 in 1997 to 7,298 in 2004. (Figure 17)

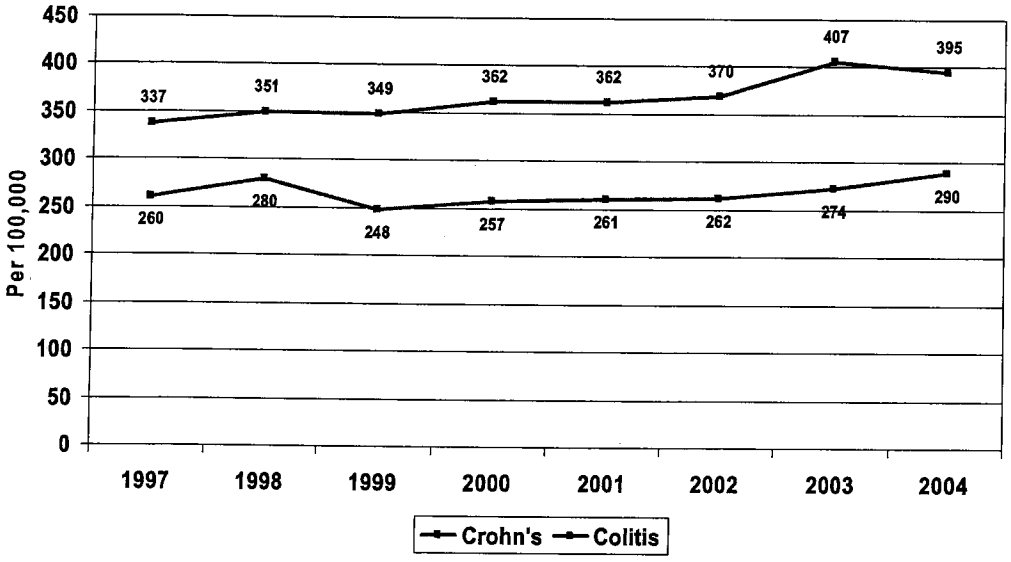
Figure 17. Number of Outpatients with Crohn's Disease and Ulcerative Colitis, Florida, 1997-2004



The 8-year overall prevalence (each patient was counted only once) was 173.1 per 100,000 people for Crohn's disease and 256 per 100,000 people for ulcerative colitis during 1997-2004. Some patients were diagnosed with both Crohn's disease and ulcerative colitis. The average prevalence of patients with Crohn's disease and/or ulcerative colitis was 412.4 per 100,000 people.

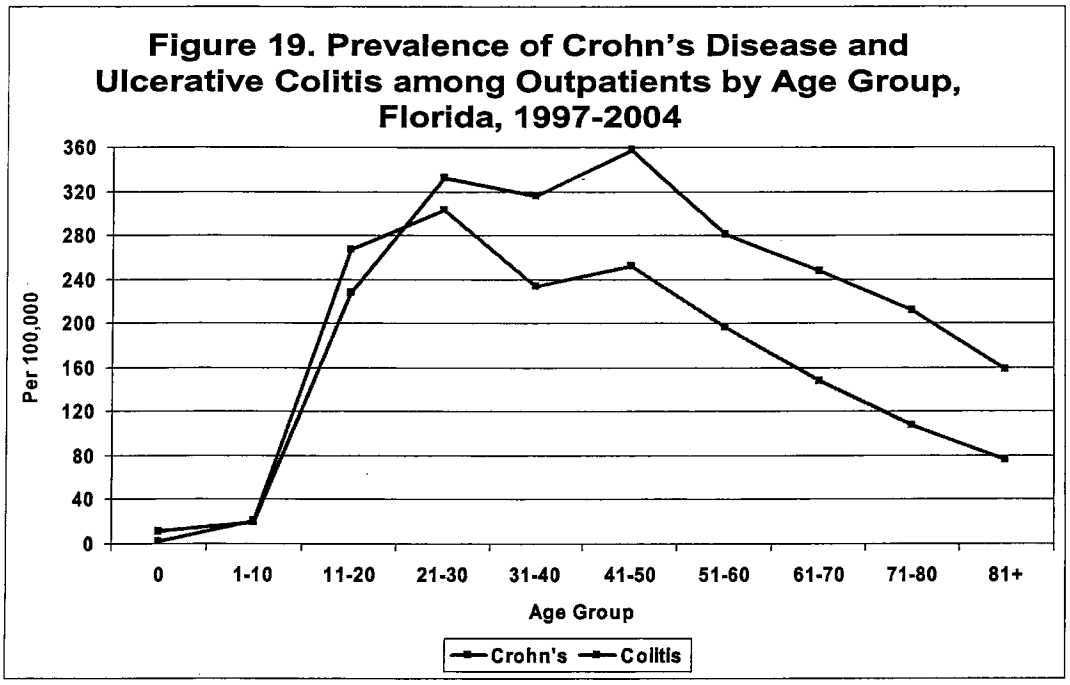
The annual prevalence of ambulatory patients increased for both Crohn's disease and ulcerative colitis in the 8-year period. The prevalence of Crohn's disease increased by 11 percent, from 260 per 100,000 persons in 1997 to 289 per 100,000 persons in 2004. The prevalence of ulcerative colitis increased by 17 percent, from 337 per 100,000 persons in 1997 to 395 per 100,000 persons in 2004. (Figure 18)

Figure 18. Prevalence of Outpatients with Crohn's Disease and Ulcerative Colitis, Florida, 1997-2004

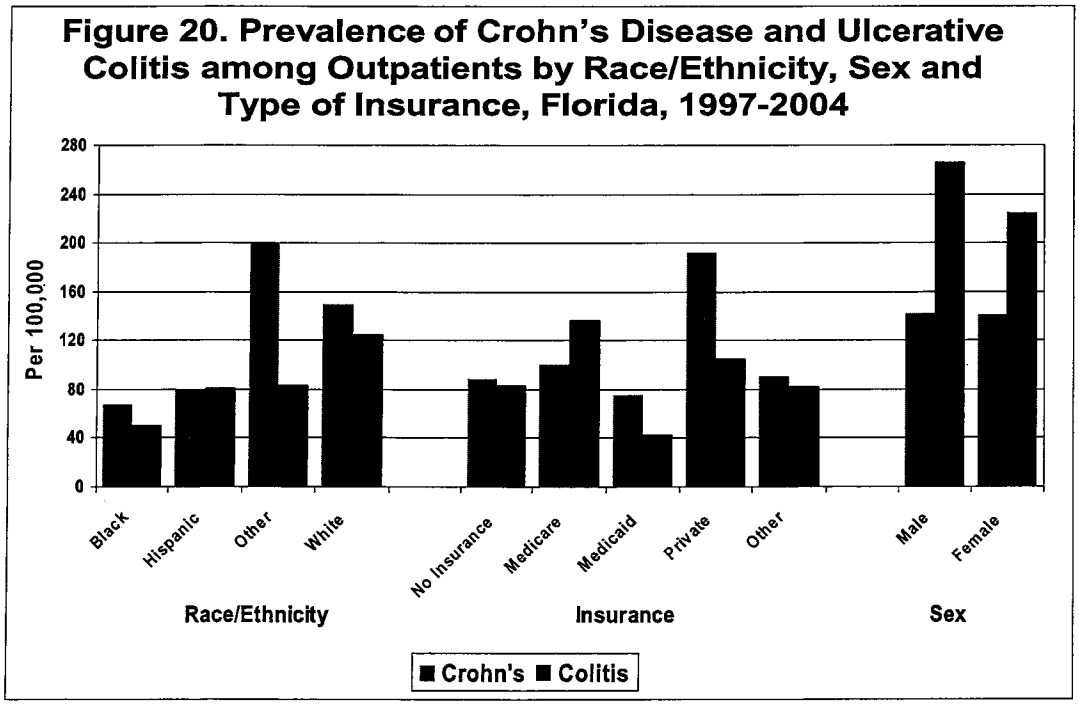


The age-specific prevalence of Crohn's disease increased dramatically in teenagers and peaked in the 21- to 30-year-old age group. Age-specific prevalence decreased among patients aged 30 years and older, with an exception of an increase in the 41- to 50-year-old age group.

The age-specific prevalence of ulcerative colitis increased among patients between ages 11 and 30 years, and then reached a peak of 358 per 100,000 persons among the 41- to 50-year–old age group. The prevalence then decreased by age among people aged 50 years and older. (Figure 19)



Patients of other races had the highest prevalence of Crohn's disease at 200 per 100,000 people. The prevalence of Crohn's disease among Whites was the second highest at 150 per 100,000 people. The prevalence of Crohn's disease was the highest among patients with a private health insurance (193 per 100,000 people). The prevalence was the lowest among Medicaid recipients (75 per 100,000 people). The prevalence of Crohn's disease was slightly higher among males (143 per 100,000 people) than among females (141 per 100,000 people). (Figure 20)

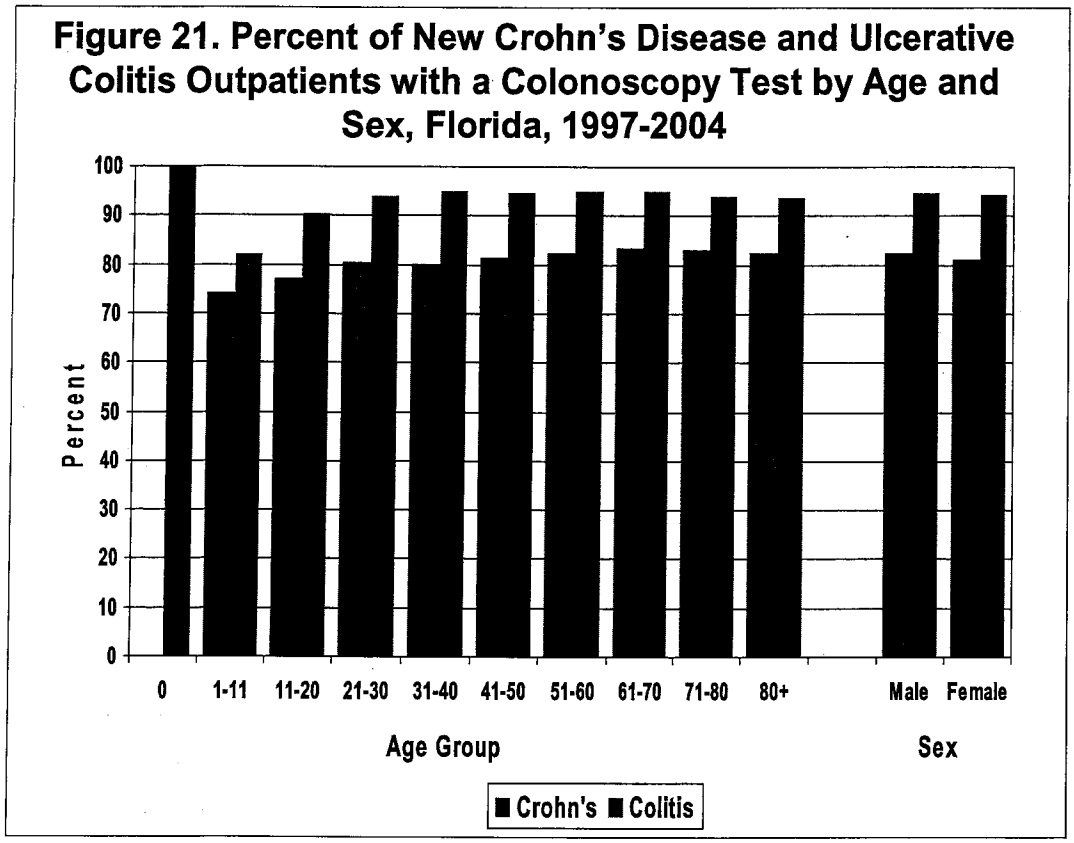


The prevalence of ulcerative colitis was the highest among Whites (125 per 100,000 people), and among Medicare beneficiaries (137 per 100,000 people). The prevalence was the lowest among Medicaid recipients (43 per 100,000 people). Males had a higher prevalence of ulcerative colitis (265 per 100,000 people) than females (224 per 100,000 people). (Figure 22)

Approximately 82 percent of Crohn's disease patients had a colonoscopy. The percent of Crohn's disease patients with a colonoscopy was lower among patients under age 20 than among older patients. The percent was the same among both males and females.

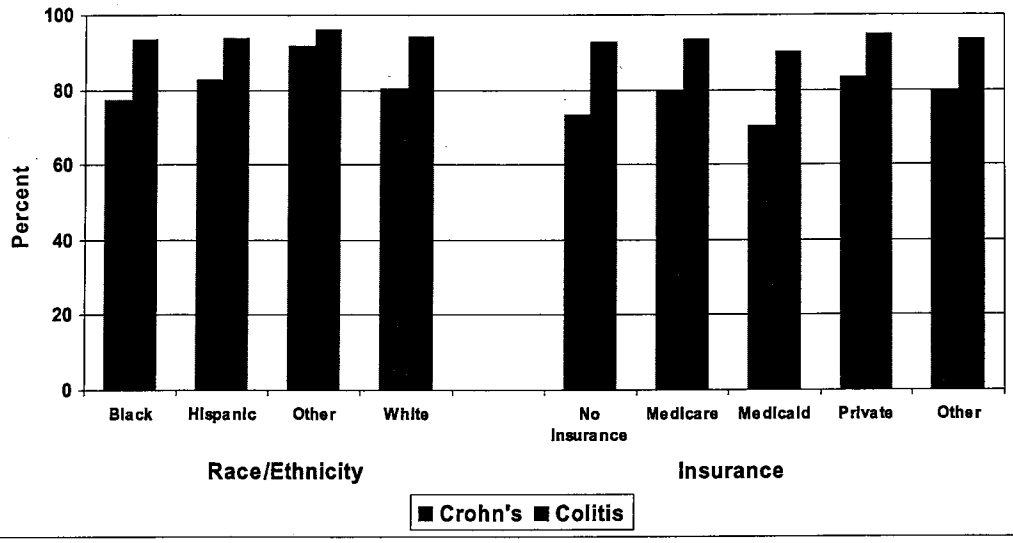
A majority (94 percent) of ulcerative colitis patients had a colonoscopy. The percent of ulcerative colitis patients with a colonoscopy was higher among patients aged 20 years and older. There was no difference in the percentage between males and females. (Figure 21)

Figure 21. Percent of New Crohn's Disease and Ulcerative Colitis Outpatients with a Colonoscopy Test by Age and Sex, Florida, 1997-2004



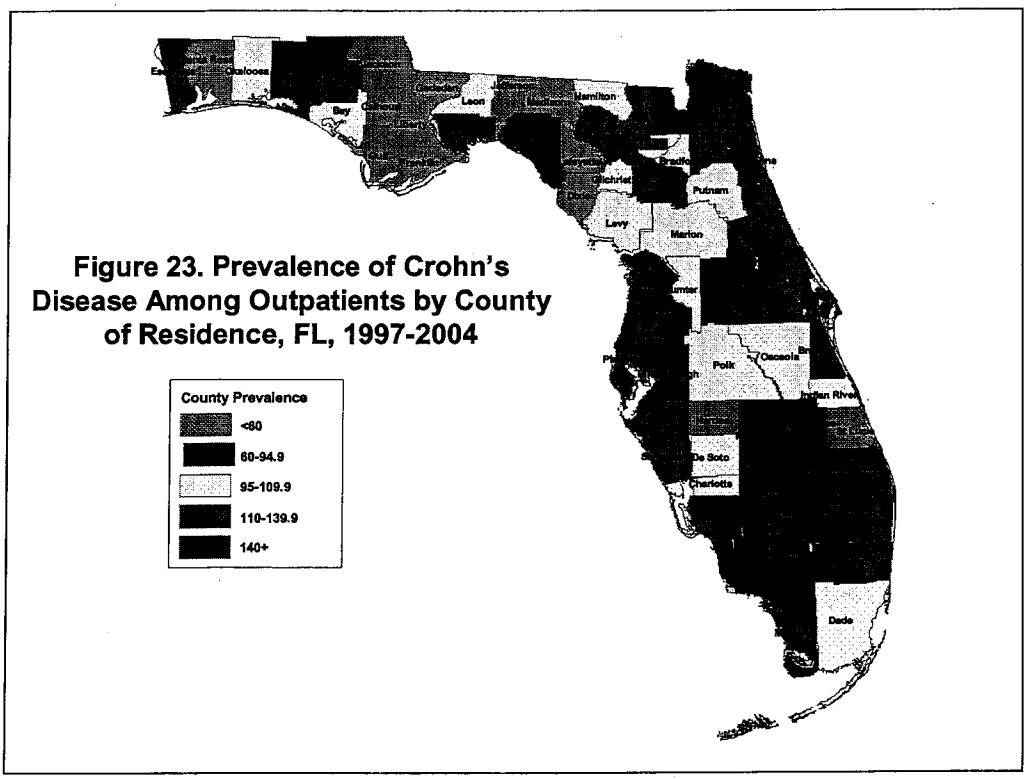
The percent of Crohn's disease patients with a colonoscopy was the highest among patients of other races (96 percent), and among patients with a private health insurance (95 percent). The percent of ulcerative colitis patients who had a colonoscopy was the lowest among Medicaid recipients (90 percent). (Figure 22)

Figure 22. Percent of New Crohn's Disease and Ulcerative Colitis Outpatients with a Colonoscopy Test by Race/Ethnicity and Type of Insurance, Florida, 1997-2004



Twelve counties had an eight-year overall prevalence of Crohn's disease of 140 per 100,000 persons or greater in Florida. These counties are Columbia, Union, Clay, Alachua, Flagler, Seminole, Pinellas, Manatee, Sarasota, Lee, Hendry, and Broward. (Figure 23) It is noteworthy that Union, Seminole, Pinellas, and Sarasota also had a high prevalence of Crohn's disease among inpatients. (Figure 15)

Figure 23. Prevalence of Crohn's Disease Among Outpatients by County of Residence, FL, 1997-2004



Thirteen counties had an overall prevalence of ulcerative colitis of 300 per 100,000 people or greater in Florida. These counties are Gulf, Leon, Jefferson, Citrus, Lake, Hernando, Seminole, Pinellas, Sarasota, Collier, Palm Beach, Broward, and Monroe. (Figure 24) Among these counties, Gulf, Citrus, Lake, Hernando, Sarasota, and Collier also had a high prevalence of hospitalization for ulcerative colitis.

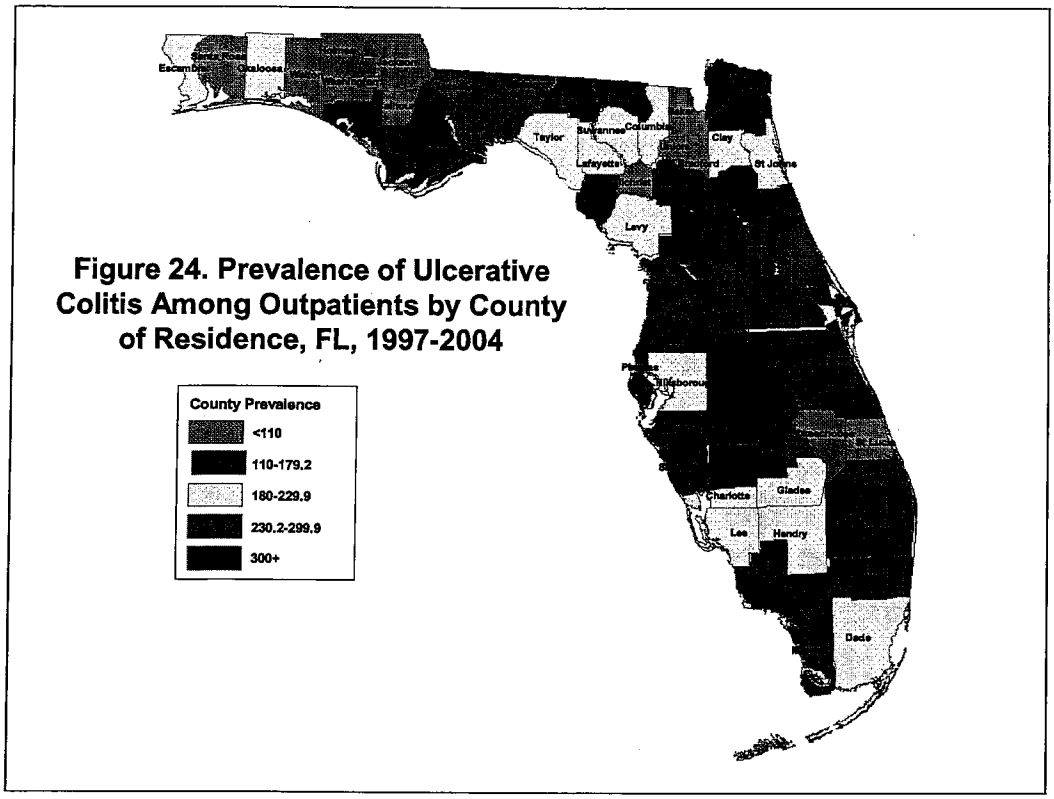


Figure 24. Prevalence of Ulcerative Colitis Among Outpatients by County of Residence, FL, 1997-2004

Seminole, Pinellas, Sarasota, and Broward counties had high prevalence rates for both Crohn's disease and ulcerative colitis among ambulatory patients.

Sarasota was the only county that had a high prevalence for both Crohn's disease and ulcerative colitis among both inpatients and ambulatory patients.

BRFSS Survey

A total of 1,678 respondents answered the survey questions in the IBD module. Excluded from the analysis were 19 respondents who answered "don't know" or "not sure." Among the 1,659 respondents included in the final analysis, 63 reported that someone in their household was diagnosed with IBD. Three (4.8 percent) of 63 households had more than one person diagnosed with IBD.

BRFSS data suggested that 3.2 percent of all households have IBD patient(s), with 4.2 percent of households among Whites, 3.4 percent of households among Hispanics, 1.6 percent of households among Blacks, and 1.7 percent of households among other races.

There was no difference in the percent of having somebody with IBD between households with annual income less than $50,000 and household with annual income of $50,000 or more.

Among the 3,066 adults and 916 children within the 1,659 households, 66 persons were reported being diagnosed with IBD. Because the BRFSS survey did not ask for the age of individuals with IBD, the DOH team estimated that two of the people with IBD were children (under age 20), based on the age distribution of hospital discharge, and ambulatory care, data. The prevalence of IBD was estimated as 2.1 percent for adults and 0.22 percent for children. These estimates were not weighted prevalence, which did not take into account of probability of survey respondents being included in the survey. A weighted prevalence will be available after CDC has completed the data weighting process.

Among survey respondents, 12 (18.2 percent) persons with IBD in 10 households were hospitalized in the past year. There was no difference in the percent of households with an IBD patient being hospitalized by race or by household income.

GI Physician Survey

The DOH received 113 completed survey questionnaires from GI physicians. The GI physicians who responded to the survey reported that 9,005 (7.3 percent) IBD patients were seen in the past 12 months among their 123,480 patients within that timeframe. Among IBD patients, approximately 14.2 percent were diagnosed in the past 12 months.

It was estimated that 40 percent of IBD patients were between the ages 20 and 45 years, and 30 percent were between the ages 45 and 65 years. IBD patients under age 20 years only accounted for approximately 10 percent.

Whites accounted for 93 percent of IBD patients; Blacks accounted for approximately 5 percent. Very few IBD patients were either Asian or other races.

Among IBD patients, females accounted for 51 percent and males for 49 percent. Approximately one quarter (22.4 percent) of patients had a family history of IBD, and one-eighth (12.2 percent) were hospitalized in the past 12 months.

The majority (94 percent) of IBD patients under the care of the responding physicians were enrolled in colon cancer surveillance.

IBD Patient Survey

The DOH received 27 completed survey questionnaires from IBD patients who voluntarily participated in the survey. The following are the results of the survey:

Age range of participants: 9 to 79 years

Age of diagnosis:

Age	<10	11-19	20-39	40-64	65 +
Percent	7.5	11	48	26	7.5

Average time living with IBD: 11.1 years

Gender: 78 percent Female 22 percent Male

Race/ethnicity: 96 percent Caucasian 4 percent Other

Jewish Decent: 33 percent yes, 63 percent no, and 4 percent unsure

Region of birth (within the US):
93 percent of respondents were born in the United States, of those:

Region	Southeast	Midwest	Northeast
Percent	28	4	68

Type of IBD:

Disease	Crohn's	Colitis	Crohn's & Colitis
Percent	56	40	4

Severity of symptoms:
78 percent of respondents reported their illness as active, of those:

Severity	Mild	Moderate	Severe
Percent	33	62	5

Family History:- 18 percent had a family history; 78 percent reported no family history of IBD; and 4 percent unsure

Proximity to cattle:
- 19 percent lived near cattle prior to diagnosis.

Smoking status:
- 30 percent of respondents were current smokers, and 67 percent lived with a smoker prior to diagnosis. The percent of current smoking among IBD patients was higher than the 2004 state average prevalence (20.2 percent).

Colonoscopy:
- 56 percent had first colonoscopy due to IBD symptoms

Other medical conditions prior to diagnosis of IBD:
- 27 percent had serious medical illnesses
- 11 percent had psychological illnesses
- 37 percent were hospitalized
- 59 percent reported having surgeries

Of those reporting surgeries:
- 25.0 percent had appendectomies; 62.5 percent had tonsillectomies; 12.5 percent had other surgeries
- Other surgeries listed: liver transplant and c-section

Assessment of overall health:

- 18 percent said their health was poor

CONCLUSIONS

The Crohn's disease and ulcerative colitis epidemiologic study was conducted by the DOH in conjunction with the University of Florida, AHCA, and BCBS, under the guidance of the Advisory Committee. This study is a large population-based study that combined multiple sources of data that covers a majority of Florida's population. The data used in this study included 42,372,600 patient claim records in up to 10 years and survey data of approximately 2,000 households, providers, and patients.

This study was the first to provide state-specific data on IBD for Florida, in terms of estimating the prevalence of Crohn's disease and ulcerative colitis, the demographic characteristics of IBD patients, and major risk factors of the IBD.

Estimated prevalence of Crohn's disease and ulcerative colitis

The Prevalence

The population-based prevalence of Crohn's disease is estimated at 222 per 100,000 people, and the prevalence of ulcerative colitis at 307 per 100,000 people. These estimates were calculated based on age distribution of Florida's population and age-specific prevalence of Crohn's disease and ulcerative colitis of BCBS members.

The BCBS data showed that the prevalence of IBD among BCBS members, including inpatients and outpatients was for:

- Crohn's disease: 220 per 100,000 persons
- Ulcerative colitis: 300 per 100,000 persons
- Other colitis: 520 per 100,000 persons

BCBS data captured information on both hospitalizations (severe disease) and clinic visits (less severe disease). BCBS data were a good source in determining the prevalence of IBD because there is less disparity in access to health care among BCBS members. However, BCBS members are not a representative sample for overall Florida population, among which approximately 17 percent of people without a health insurance.

The estimates based on BCBS data were consistent with findings from previous epidemiologic studies in North America, which suggested population-based prevalence varied from 162 per 100,000 people to 199 per 100,000 people for Crohn's disease and from 170 per 100,000 people to 246 per 100,000 people.

The combined hospital discharge data and ambulatory patient data showed that, among patients treated in hospitals, the prevalence of:

- Any IBD: 2,737.8 per 100,000 people (or 2.74 percent)
- Crohn's disease and/or ulcerative colitis: 633.4 per 100,000 people
- Crohn's disease: 293.3 per 100,000 people
- Ulcerative colitis: 364.2 per 100,000 people

The prevalence of Crohn's disease and ulcerative colitis among inpatients and ambulatory patients was 32 percent and 19 percent, respectively, higher than the prevalence among BCBS members. The difference in prevalence might reflect a compositional difference of populations between hospital patients and BCBS members.

The prevalence of IBD among Medicaid recipients was lower than that among BCBS members the prevalence of patients with:

- Crohn's disease: 61 per 100,000 people.
- Ulcerative colitis: 26 per 100,000 people.
- Other colitis: 2,200 per 100,000 people.

The causes of low prevalence of IBD among Medicaid recipients were unknown based on the data of this study. More studies are needed to examine further the contribution factors of low prevalence of IBD, including access to health care and composition of the Medicaid population.

The BRFSS survey was unable to distinguish type of IBD due to the nature of a telephone survey of the general public. An overall prevalence of IBD was estimated as 2.1 percent for adults and 0.22 percent for children. The BRFSS data represented population-based estimates, although the estimate was un-weighted and might carry large sample errors due to small sample size. The estimate was in line with other data in this study.

Number of Patients

It is estimated that approximately 35,500 Floridians have Crohn's disease and 49,000 have ulcerative colitis based on the estimated prevalence.

Hospitals in Florida served approximately 4,285 Crohn's disease patients and 5,450 ulcerative colitis patients either as inpatients or as ambulatory patients every year, accounting for approximately 12 percent and 11 percent of Crohn's disease and ulcerative colitis patients, respectively.

Demographic Characteristics

Age

The prevalence of Crohn's disease was relatively low among children and the elderly (age 70 years and older). The majority of IBD patients were diagnosed between the ages 11 and 40. The prevalence increased with age until age 50, then decreased with age.

The age-distribution might vary by population depending on the source of data. For example, the age-specific prevalence of ulcerative colitis among Medicaid recipients began to decrease among people age 50 years and older, which might reflect the fact that most Medicaid recipients were under age 50. On the other hand, the age-specific prevalence did not decrease until age 80 and older among hospital inpatients, among whom there were more elderly.

Sex:

The overall prevalence was very close between males and females, with a slightly higher prevalence among females than among males.

Both BCBS and Medicaid are population-based data that show a slightly higher prevalence of IBD among females than among males. However, the prevalence was slightly higher among males than among females for patients seen in hospitals, which might be due to the sex-distribution of hospital patients (more male patients than female patients are seen in hospitals).

Race/ethnicity:

Non-Hispanic Whites had a higher prevalence than non-Hispanic Blacks, Hispanics, and people of other races. Crohn's disease and ulcerative colitis occurred in all racial/ethnic groups.

Household Income:
No difference in prevalence by household income was found according to data from the BRFSS survey.

Type of Health Insurance:
Patients who were Medicare beneficiaries or who had private insurance had a higher prevalence rate of Crohn's disease or ulcerative colitis. Medicaid recipients had the lowest prevalence for both Crohn's disease and ulcerative colitis.

Type of medical insurance was the only variable available in the claim data and might be a surrogate indicator of socioeconomic status. The difference in prevalence might be attributable to the disparity in access to health care and the difference in race and age composition of the populations.

Residential County:
Based on hospital discharge data and ambulatory patient data, the following counties had high prevalence rates:

- Pinellas, Sarasota, and Seminole had a high prevalence of Crohn's disease.
- Citrus, Collier, Gulf, Hernando, Lake, and Sarasota had a high prevalence of ulcerative colitis.

Among BCBS members, those who resided in Glades and Wakulla counties had a high prevalence of Crohn's disease, and those who resided in Wakulla and Liberty counties had a high prevalence of ulcerative colitis.

Sarasota and Palm Beach counties were the only two counties that had a high prevalence of Crohn's disease and ulcerative colitis in all hospital discharge data, ambulatory patient data, and BCBS data.

Risk factors

Previous epidemiologic studies on risk factors of Crohn's disease and ulcerative colitis suggested that although genetic factors might be strongly associated with IBD, environmental factors would explain most variations in the prevalence of IBD. The data in this study supported the findings from previous studies.

Genetic factors

A family history was found among approximately 20 percent of patients from the patient survey, physician survey, and BRFSS survey. Both claim data and survey data indicated that the majority of patients were non-Hispanic White. The patient survey data showed that nearly two thirds of IBD patients were born in the Northeast region of the U.S. and many of IBD patients were of Jewish descent.

The consistency of the finding of family history across surveys and aggregation of IBD in a population indicated a strong association between genetic factors and occurrence of IBD.

Environmental factors

Previous studies suggested several environmental risk factors, including cigarette smoking, consumption of milk, contact with cattle, and receiving certain types of surgery, might be associated with IBD. However, none of these environmental risk factors has been confirmed.

In this study, the DOH surveyed a small group of IBD patients for these potential risk factors. The survey found that the prevalence of cigarette smoking was higher than the state's average prevalence. Many patients were exposed to second-hand smoke, and had surgical procedures, such as tonsillectomy and appendectomy. However, because of the nature of the survey (a self-reported survey without a control group) and small sample size of the survey, no causal relationship could be established between these risk factors and IBD.

Recommendations for Future Studies

This study collected a great deal of data about IBD, and laid a foundation for future studies about IBD in Florida. To better assess IBD and to serve IBD patients in Florida, more studies are needed to:

- Increase sample size for the BRFSS survey to obtain a more accurate estimate of the population-based prevalence of IBD.
- Conduct a case-control study to identify risk factors of IBD.
- Develop an IBD patient voluntary registry through healthcare providers. This registry will provide data for a longitudinal follow-up study of IBD patients and many other studies on treatment, outcome, and patient's quality of life.

ATTACHMENTS

Attachment 1: GI PHYSICIAN SURVEY

A Survey about Inflammatory Bowel Disease Patients

The purpose of this survey is to collect data on inflammatory bowel disease patients, particularly for those who may not have been hospitalized. **All data collected from this survey will be kept strictly confidential.** Please give your best approximation for the following questions.

1. How many patients have you seen in the past 12 months? (please check one)
   □ <100 □ 100-499 □ 500-999 □ 1000-1499 □ 1500 and more

How many of your patients are diagnosed with an Inflammatory Bowel Disease, such as Crohn's disease or ulcerative colitis? ____ ____

2. Please **estimate** the number of IBD patients from question 2 for the following:

Age	<20 yrs	20-44 yrs	45-64 yrs	65 yrs and older
# Patients				

Race	White	Black	Asian	Other
# Patients				

Sex	Male	Female
# Patients		

Ethnicity	Hispanic	Non-Hispanic
# Patients		

3. Among those IBD patients, how many have been hospitalized for IBD in the past 12 months?
   ____ ____

4. How many of your patients with IBD report a family history of the illness?
   ____ ____

5. Among all IBD patients, about how many were diagnosed within the past 12 months?
   ____ ____

6. Do you enter your IBD patients into the colon cancer surveillance program?
   ____yes____no

7. Please provide any additional information or comments about your IBD patients:
   _____
   _____
   _____

Thank you very much for completing the survey. Your information will greatly assist our study. In case we need to contact you for further information, please provide the following information:

Your name: _____
Your office phone number: ( ) _____-_____

Attachment 2: IBD PATIENT SURVEY

Inflammatory Bowel Disease Patient Questionnaire

Dear Respondent: As you may be aware, the Florida Department of Health is conducting a study to uncover the potential role of genetic and environmental risk factors associated with Inflammatory Bowel Disease (as mandated by House Bill 869, also known as the "Crohn's & Colitis Disease Research Act"). This is a short survey designed to evaluate potential genetic and environmental exposures for patients with IBD. If you have been diagnosed with IBD, please answer the following questions to the best of your ability. You are not obligated to answer every question, though we kindly ask that you answer as many questions as you feel comfortable in giving a response. **All information provided will remain confidential**. We are not asking for any personal identifiers (such as name, date of birth, or social security number), to ensure that your information is also anonymous. You are an invaluable resource in the development of this area of research. Your time, effort, and comments are greatly appreciated. If you have any questions or comments about this study, please contact the Crohn's & Colitis Research Coordinator at the Florida Department of Health, (850) 245-4444 extension 2424.

1. Current age:

2a. Age at Diagnosis of Inflammatory Bowel Disease:
1) 10 or under 2) 11-19 3) 20-39 4) 40-64 5) 65 or older

2b. Time you have lived with the disease in years (or months if less than 1 year):

3. Gender: 1) Male 2) Female

4. Ethnicity: 1) Caucasian 2) African American 3) Asian 4) Hispanic 5) Other:

5. Are you of Jewish descent? 1) Yes 2) No 3) Partly 4) Don't know/unsure

6a. Do you have:
1) Ulcerative Colitis 2) Crohn's Disease 3) Both CROHN'S DISEASE & ULCERATIVE COLITIS 4) Unsure

6b. Where is your disease located?
1) small intestine 2) large intestine 3) both small and large intestines
4) other 5) unsure

6c. Currently, is your disease active? 1) No 2) Yes
If yes, would you say your symptoms are: 1) mild 2) moderate 3) severe

7a. Do you have a family member who is also diagnosed with an IBD?
1) No 2) Yes

7b. If yes, please select all who have been diagnosed:
1) Mother 2) Father 3) Brother 4) Sister 5) Your child/children 6) Other:

8a. Were you born in the United States? 1) Yes 2) No

8b. If yes, what area of the United States were you born?
1) NorthEast 2) SouthEast 3) Midwest 4) NorthWest 5) SouthWest

9. Before you were diagnosed with an IBD, did you live near cattle? 1) Yes 2) No

10. Before you were diagnosed with an IBD, did you smoke cigarettes regularly, meaning on most or all days?
1) Yes-# of years: 2) No

11a. Before you were diagnosed with an IBD, did the other people living in your residence smoke cigarettes? 1) No 2) Yes

11b. If yes, please list the number of years you lived in this residence prior to your diagnosis:

12a. Did you receive a colonoscopy before you were diagnosed with an IBD?
1) Yes 2) No 3) Unsure

12b. If yes, was your first colonoscopy a result of your IBD symptoms?
1) Yes 2) No 3) Unsure

13a. Before you were diagnosed with an IBD, did you have any of the following:

Medical illnesses	1) Yes 2) No 3) Don't know/unsure
Psychological illnesses	1) Yes 2) No 3) Don't know/unsure
Medical hospitalizations	1) Yes 2) No 3) Don't know/unsure
Surgeries	1) Yes 2) No 3) Don't know/unsure

13b. Before you were diagnosed with an IBD, did you have any of these procedures:

Appendectomy	1) Yes 2) No 3)Don't know/unsure
Tonsillectomy	1) Yes 2) No 3) Don't know/unsure
Other (please list):	

14. In general, would you say your health is: 1) Excellent 2) Good 3) Average 4) Poor

Florida Council for Community
Mental Health

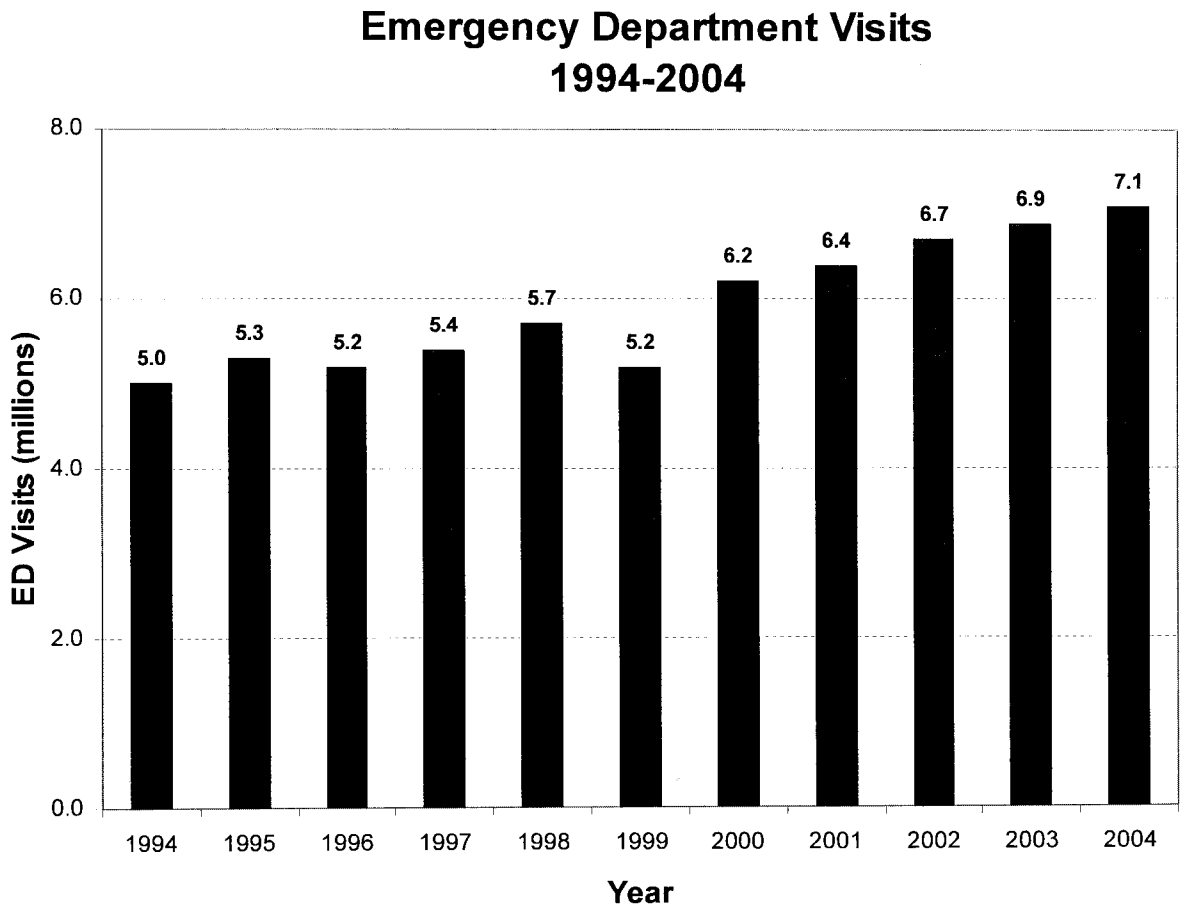
Emergency Psychiatric Care
A Community Crisis

House Health Care Committee
February 22, 2006
Florida Council

Emergency Department (ED) Use
The Facts

- In 2004, there were 7.1 million ED visits in Florida; 1.3 million resulted in hospital admissions (AHCA, 2006).
- From 1994 to 2003, visits increased by 26.2% in the U.S. (AHCA, 2006).
- Between 1994-2004, the number of ED visits in Florida increased by 40.9%, while there was a 5.3% decrease in the number of EDs (AHCA, 2006).
- Accounting for increases in population, the visit rate per 1,000 persons increased by 12.9% over the same period (AHCA, 2006).

Florida Emergency Department Visits



Source AHCA Hospital Financial Database

Emergency Department (ED) Use The Facts

- In 2004, total ED charges in Florida were $4.4 billion, a 457.0% increase from 1994 [$791 million]; the average charge per visit was $619 (AHCA, 2006).
- The average ED wait time in Florida is 3 hours (AHCA, 2006); half of ED patients nationally spend 2-6 hours in the ED (CDC, 2005).
- The number of EDs per 1 million people in Florida: 7.82 – 47th in the nation (ACEP, 2006).
- Florida's rank on access to emergency care: C- [41st in nation] (ACEP, 2006); overall Florida ED Rank: C- (ACEP, 2006).
- Nationally, 62% of emergency departments are at or over capacity; one-half of urban EDs are at over capacity (AHCA, 2002).

Emergency Department (ED) Use Psychiatric Disorders

- ED use by those with psychiatric/substance abuse disorders constitutes a significant and growing burden on hospital EDs.
- Two million people visited EDs for psychiatric care in the U.S. in 2002 (NCHS, 2003).
- Many hospital EDs are ill equipped to meet the needs of patients with psychiatric disorders because of inadequate numbers of psychiatric practitioners and beds in many EDs.
- Nationally, from 1992 to 2001, mental health-related ED visits increased from 4.95 to 6.3% of total ED visits and increased from 17.1 to 23.6 visits per 1,000 population (Larkin et al, 2005).

Emergency Department (ED) Use Psychiatric Disorders

- In a 2004 survey conducted by the American College of Emergency Physicians, 60% of physicians reported that the increase in psychiatric ED patients is:
  - negatively affecting access to emergency medical care for all patients;
  - causing longer wait times;
  - fueling patient frustration;
  - limiting the availability of hospital staff; and
  - decreasing the overall availability of ED beds (ACEP, 2006).
- Two-thirds of emergency physicians attribute the recent escalation of psychiatric patients to budget cutbacks and the decreasing number of psychiatric beds (ACEP, 2006).

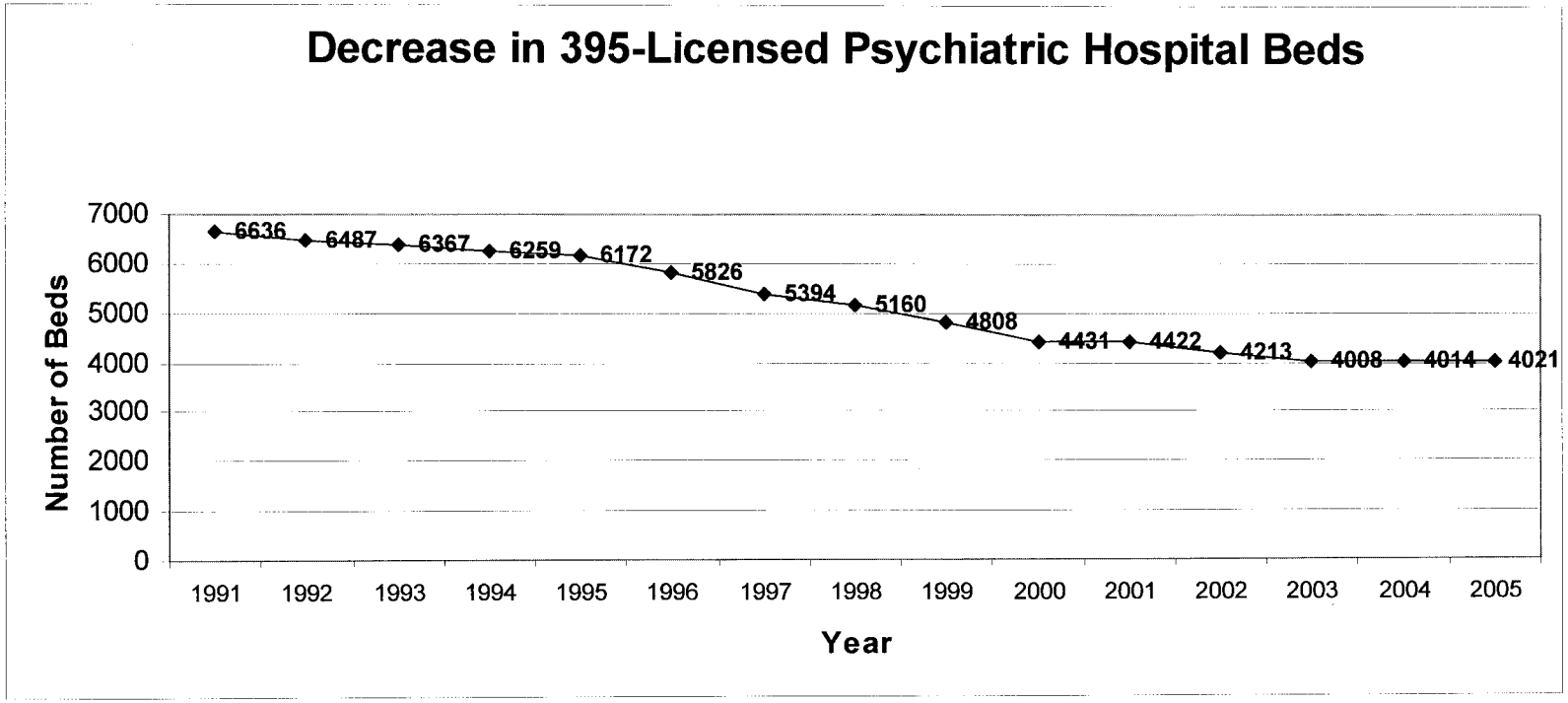
Emergency Department (ED) Use Psychiatric Disorders

- Significant predictors of high ED utilization: prior number of ED visits, prior number of hospitalizations, and history of depression, psychoses, alcohol abuse, and homelessness.
- At a 6.4% prevalence rate, Florida's EDs treat an estimated 1,245 patients with psychiatric disorders every day or more than 454,000 visits/year.
- Homeless individuals account for 30 percent of ED use for psychiatric emergency care; 33% of homeless individuals have one or more ED encounters annually.
- Homeless individuals are more likely than other emergency service patients to have multiple episodes of service and to be hospitalized after the emergency department visit.

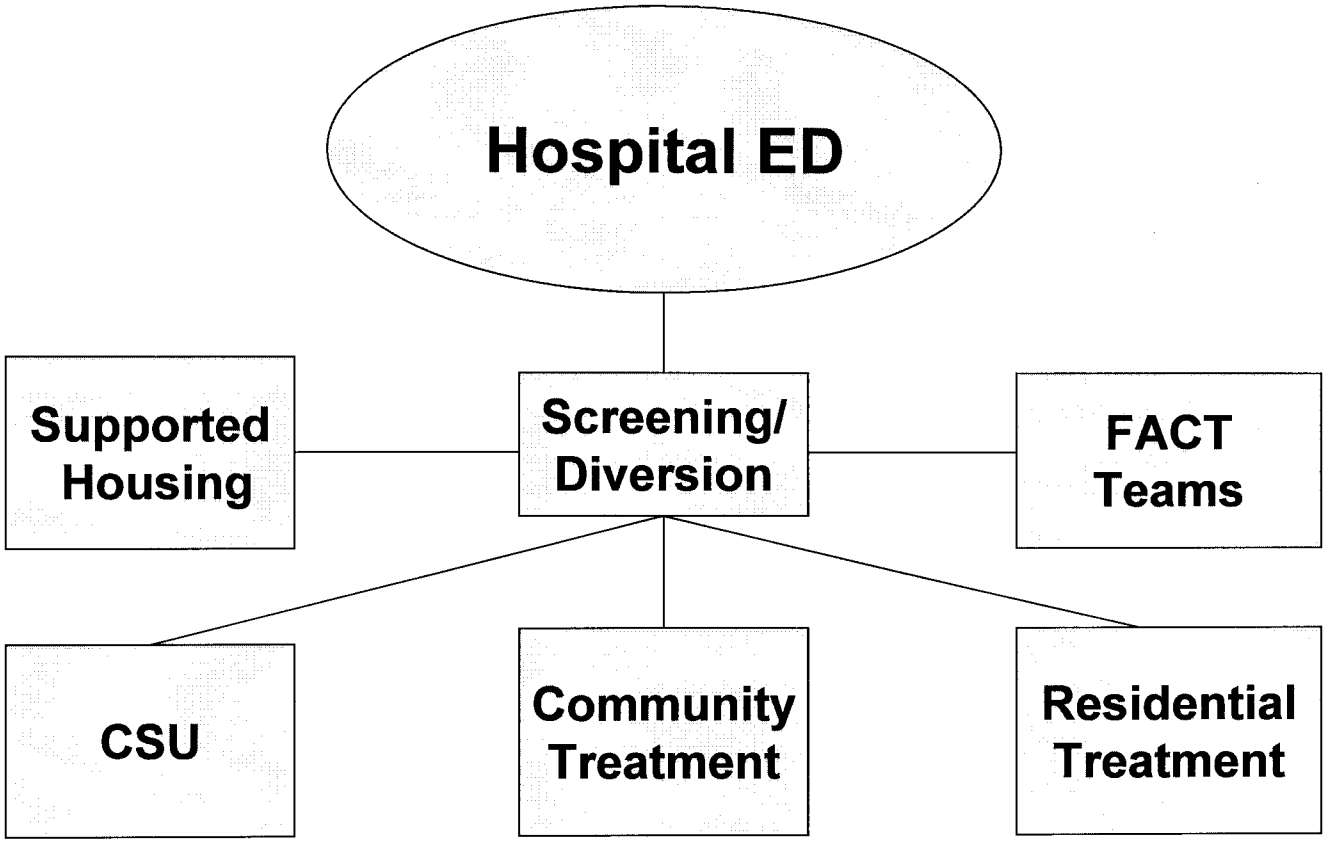
Acute and Emergency Care Issues

- Psychiatric and substance abuse patients represent the 'frequent flyers' and a disproportionate share of total ED visits.
- Increases in ED boarding.
- Reduction in overall psychiatric acute care bed supply and an underfunded publicly financed acute and emergency care system.
- Shortage of CSU and short-term residential beds.
- ED "revolving door" because of lack of post-discharge services.
- Shortage of low-income housing; unstable housing.
- Lack of Medicaid and DCF financed community treatment (crisis and recovery-based services).

Acute and Emergency Care Issues



A New Cost-Effective Approach to Acute and Emergency Psychiatric Care



Crisis Stabilization Units

- Crisis Stabilization Units (CSUs) provide brief psychiatric intervention for low-income individuals with acute psychiatric conditions who are a danger to themselves or others.
- CSU stays average 3 days; 90% of admissions are involuntary and a result of law enforcement intervention.
- CSUs may screen, assess, and admit for stabilization persons who are voluntarily or involuntarily placed pursuant to Chapter 394, F.S.
- Clients may be provided 24-hour observation, medication, and other appropriate services.
- CSUs must provide services regardless of the client's ability to pay and shall be limited in size to a maximum of 30 beds.

Crisis Stabilization Units

- Florida has 45 public receiving facilities with 923 DCF-purchased CSU beds (765 adult beds and 158 children beds); there are 477 Medicaid reimbursable hospital psychiatric beds (306 adults and 171 children's beds).
- DCF estimates that Florida needs 10 CSU beds per 100,000 population.
- Adult Bed Need: 1,395
- Unmet Need: 324 Beds (1,395-[765+306])
- CSU Rates: $292 – no rate increase since 1999 (Recommended rate: $358).
- Additional Funding: $30.6 Million for Beds/$16.1 Million for Rates (75% State-25% Local).

Short-Term Residential Treatment Facilities (SRTs)

- SRTs provide residential care for up to 90 days for individuals experiencing an acute mental health crisis.
- SRT Beds in Florida: 269
- SRT Facilities in Florida: 11
- No SRTs Located in Districts 1, 2, 4, 8, 9, and 13.
- Need: Additional SRTs/SRT Beds

Community Treatment – Unmet Needs

- Prevalence of SPMI Adults: 5.4% (13.9M x .054 = 753,068 x. 33 (SPMI and Seek Treatment – Currently Served [130,702]).
- Unmet Adult Need: 120,070
- Prevalence of SED Children: 7.9% (4.1M x. .079 x .286 (uninsured) x .36 require public coverage.
- Unmet Child Need: 161,654 (207,205- 45,551 [currently served])
- $ Needed: Adults - $136.9M; Children - $97.0M
- Florida ranks 47th in per capita state spending on mental health care.
- ED use drops by 50+% with community treatment.

Assertive Community Treatment

- Florida has 32 FACT Teams.
- The annual cost of a FACT Team is $1,254,394; total appropriation is $40.1 million.
- Each team serves 100 individuals; 60% are Medicaid eligible.
- Total FACT Team capacity statewide – 3,200 individuals; average monthly caseload in 9/05 was 2,844 – 94% of statewide capacity.
- ACT Findings: ED use down 32-50%, hospitalization down 58-78%; ACT highly successful in engaging individuals in treatment, increasing housing stability and improving symptoms.
- Needs: Additional FACTs (Adult, Children, Forensic) and Rate Increases.

Model Programs

- San Francisco General Hospital Frequent User Program/ED Case Management Program/Crisis Resolution Team
- Boston Health Care for the Homeless Project
- Comprehensive Psychiatric Emergency Programs (Maryland, New York)
- Psychiatric Emergency Response Team/Services (Multiple Sites)
- Orlando Community Receiving Center
- Mobile Crisis Teams (Multiple Sites)
- Crisis Family Care (Multiple Sites)
- Crisis Care Center (San Antonio)
- Assertive Community Treatment (Multiple Sites)
- Jail Diversion Programs (Multiple Sites)

Recommendations

- Assess Acute and Emergency Psychiatric Care Needs in Florida; Determine Effect of Psychiatric Emergency Care on ED Overcrowding
- Expand CSU Capacity – Increase Beds/Increase Rates
- Expand Short-Term Residential Capacity
- Expand FACT Teams
- Close the Treatment Gap/Achieve Funding Equity
- Increase Permanent and Supported Housing
- Create Integrated Systems of Care